

## **Collaborative Rulemaking Discussion** Implementation of E2SSB 5367 (THC Bill) Rulemaking

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## Welcome

**Reason Rulemaking is Necessary**: To amend the current rules (chapter 314-55 WAC) to implement the provisions of E2SSB 5367 ("THC bill").

**Meeting Goal**: Review and discuss regulatory policy options to align the current rules with the statutory changes, keeping mind factors such as benefits, costs, direct and/or indirect impacts, laboratory and/or testing considerations, and possible unintended consequences.



#### Rulemaking Timeline All dates are *tentative*.

April 2024 –

Public Hearing





### **THC Bill Background**

- Bill Title: Engrossed Second Substitute Senate Bill (E2SSB 5367) (Chapter 365, Laws of 2023), "An Act relating to the regulation of products containing THC."
  - Agency (LCB) sponsored legislation to regulate intoxicating products containing THC and distinguish between a "cannabis product" and "hemp consumable," subsequently expanded LCB's authority to regulate products with any detectable amount of THC.
  - Effective date of legislation July 23, 2023
  - Final bill text pdf
- Amended sections (chapter 69.50.RCW):
  - <u>RCW 69.50.101</u> *Definitions*.
  - <u>RCW 69.50.326</u> Cannabis producers, processors—Use of additives to enhance CBD concentration of authorized products—Rules.
  - <u>RCW 69.50.346</u> Labels on retail products.
- New sections (chapter 69.50.RCW): :
  - <u>RCW 69.50.3251</u> Cannabis manufacture, sale, distribution prohibited without a license—Tribal agreements—Synthetic cannabinoids prohibited.
  - <u>RCW 69.50.326</u> (**NOTES**) Cannabis producers, processors—Use of additives to enhance CBD concentration of authorized products—Rules.



### **Overview of THC Bill Provisions**

- Amended <u>RCW 69.50.101</u> Definitions.
  - Amended definitions:
    - "Cannabis"
    - "Cannabis products"
    - "THC concentration"
  - New definitions:
    - "Package"
    - "Unit"
- Amended <u>RCW 69.50.326</u> Cannabis producers, processors Use of additives to enhance CBD concentration of authorized products.
  - New <u>RCW 69.50.326 (Notes)</u> States an Agency is not required to purchase liquid chromatography-mass spectrometry instruments.
- Amended <u>RCW 69.50.346</u> Labels on retail products.
- **Created new section** <u>RCW 69.50.3251</u>. Cannabis manufacture, sale, distribution prohibited without a licdense Tribal agreements Synthetic cannabinoids prohibited.



## Amended definition of "THC concentration"

## E2SSB 5367 amended the definition of *"THC concentration"* to include forms of THC, in addition to <u>delta-9 THC</u>.

- Under the current rules, *delta-9 THC* is the only form of THC required for potency analysis (WAC 314-55-102(3)(a)).
- The formula for *total THC* calculates only the *total delta-9 THC*.
  - WAC 314-55-102 Quality Assurance and Quality Control. (3)(a)(i)(A) "Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA: M total delta-9 THC = M delta-9 THC + (0.877 × M delta-9 THCA)."
- <u>RCW 69.50.346(1)(c)</u> requires labels on cannabis product packages sold at retail to include the THC concentration of the product.
  - WAC 314-55-105 requires product labels sold at retail to include the total THC using the formulas referenced in WAC 314-55-102.



Amending current rules to align with new statutory definition of "THC concentration" Regulatory Options to Consider

- ✓ **Option #1**: Do not amend current rules.
  - Require potency analysis to include only delta-9 THC, and continue calculating total THC based on only delta-9 THC, and
  - Require "THC concentration" to be reported on retail product labels as 'total [delta-9] THC'.
- ✓ Option #2: Amend rules to include other forms of THC, in addition to delta-9 THC, in "THC concentration."
  - Require potency analysis to include other forms of THC, in addition to delta-9 THC (e.g., delta-8 THC, THC-P, THCV, etc.).
  - Require retail product labels to include other forms of THC detected during potency analysis, and either:
    - a) Amend formula to calculate 'total THC' to include all forms of THC detected during potency analysis
      - i. <u>Example formula</u>: Amend formula to calculate 'total THC' to include all forms of THC detected during potency analysis: Total THC (mg/g) = [(delta 8-THCA concentration (mg/g) + delta 9-THCA concentration (mg/g)) x 0.877] + [delta 8-THC concentration (mg/g) + delta 9-THC concentration (mg/g) + THCVA (mg/g)) x 0.877] + [delta 8-THC concentration (mg/g) + delta 9-THC concentration (mg/g) + THCVA (mg/g)) x 0.877] + [delta 8-THC concentration (mg/g) + delta 9-THC concentration (mg/g) + THCVA (mg/g)) x 0.877] + [delta 8-THC concentration (mg/g) + delta 9-THC concentration (mg/g) + THCVA (mg/g)) x 0.877] + [delta 8-THC concentration (mg/g) + delta 9-THC concentration (mg/g) + THCVA (mg/g)) x 0.877] + [delta 8-THC concentration (mg/g) + delta 9-THC concentration (mg/g) + THCVA (mg/g)) x 0.877] + [delta 8-THC concentration (mg/g) + delta 9-THC concentration (mg/g) + THCVA (mg/g)) x 0.877] + [delta 8-THC concentration (mg/g) + delta 9-THC concentration (mg/g) + THCVA (mg/g)) x 0.877] + [delta 8-THC concentration (mg/g) + delta 9-THC concentration (mg/g) + THCVA (mg/g) + THCVA (mg/g) + THCVA (mg/g) + THCVA (mg/g) + delta 9-THC concentration (mg/g) + delta 9-THC
    - b) Calculate 'total THC' for each form of THC detected during potency analysis; or
      - i. Example formula: Total delta-9 THC = (% delta-9 THCA x 0.877) + % delta-9 THC and Total delta-8 THC = (% delta-8 THCA x 0.877) + % delta-8 THC
    - c) Remove all references to 'total THC' throughout the rules and replace with "THC concentration."
      - i. Require THC concentration to be reported on retail product labels for useable cannabis and cannabis concentrates to be expressed as a percentage, for each form of THC detected during potency analysis; and
      - ii. Require THC concentration to be reported on retail product labels for cannabis-infused products (solid, liquid, and topical) to be expressed in milligrams, for each form of THC detected during potency analysis.



## Amended definition of "cannabis products"

E2SSB 5367 amended the definition of "cannabis products" to include products containing "any detectable amount of THC," whereas "cannabis products" was previously defined as products with a THC concentration greater than **0.3% delta-9 THC**.



Amending current rules to align with new statutory definition of *"cannabis products"* – Establishing a limit of detection for THC Regulatory Options to Consider

- ✓ Option #1: The limit of detection (LOD) is <u>0.3 mg/g.</u>
  - 0.03% or 300 ppm
  - LOD corresponds with current limit of quantification (LOQ) in rule, 1.0 mg/g.
  - Recommendation from Cannabinoid Science Workgroup

#### ✓ Option #2: The LOD is 0.02 mg/g.

- 0.002% or 20 ppm
- ✓ Option #3: The LOD is 0.001 mg/g.
  - 0.0001% or 1 ppm

✓ Option #4: Do not include an LOD in rule and require compliance with a third-party standard (i.e., AOAC)



New and amended section – Prohibiting synthetic cannabinoids

E2SSB created a new section, <u>RCW 69.50.3251</u>, prohibiting the producing, processing, manufacturing, and sale of **any synthetically** *derived cannabinoid or completely synthetic cannabinoid;* and amended <u>RCW 69.50.326</u> to prohibit the use of a synthetic cannabinoid to be used as an additive to enhance the CBD concentration of a product.



# Amending current rules to align with statutory changes related to prohibiting synthetic cannabinoids

#### Regulatory Options to Consider

✓ Option #1: Do not amend current rules.

 Default to dictionary definition - "Synthetic" means of, relating to, or produced by chemical or biochemical synthesis especially: produced artificially synthetic drugs and synthetic silk. – Merriam Webster dictionary

#### ✓ **Option #2:** Create a new definition for *"synthetic," "synthetically-derived,"* and/or *"semi-synthetic."*

- Example language:
  - "Synthetic cannabinoid" means any cannabinoid that does not occur in the cannabis plant and is produced through chemical manipulation in a laboratory or similar facility.
  - "Artificially derived cannabinoid" means a chemical substance that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from the cannabis plant. "Artificially derived cannabinoid" does not include: (i) a naturally occurring chemical substance that is separated from the cannabis plant by a chemical or mechanical extraction process; or (ii) a cannabinoid that is produced by decarboxylation from a naturally occurring cannabinoid acid without the use of a chemical catalyst.
  - "Manufactured cannabinoid" means cannabinoids naturally occurring from a source other than marijuana that are similar in chemical structure or physiological effect to cannabinoids derived from cannabis, as defined in RCW 69.50.101, but are derived by a chemical or biological process.
  - "Synthetic cannabinoid" means any material, compound, mixture or preparation which contains any quantity of a substance having a psychotropic response primarily by agonist activity at cannabinoid-specific receptors affecting the central nervous system that is produced artificially and not derived from an organic source naturally containing cannabinoids.
  - "Synthetic cannabinoid" does not include the thermo-chemical conversion of cannabinoids in their acidic form into their neutral form.



# Thank you!