



PROPOSED RULE MAKING

CR-102 (December 2017) (Implements RCW 34.05.320)

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FILED

DATE: August 22, 2018

TIME: 10:56 AM

WSR 18-17-184

Agency: Washington State Liquor and Cannabis Board

Original Notice

Supplemental Notice to WSR _____

Continuance of WSR _____

Preproposal Statement of Inquiry was filed as WSR 18-08-092 on April 4, 2018 ; or

Expedited Rule Making--Proposed notice was filed as WSR _____; or

Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or

Proposal is exempt under RCW _____.

Title of rule and other identifying information: (describe subject)

New Section, WAC 314-55-109, Cannabinoid additives – Requirements, restrictions, and quality assurance testing.

Hearing location(s):

Date: **Time:** **Location:** (be specific) **Comment:**

October 3, 2018	10:00 a.m.	Washington State Liquor and Cannabis Board, Board Room 3000 Pacific Ave SE Olympia, WA 98504	
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Date of intended adoption: On or after October 17, 2018 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: Joanna Eide, Policy and Rules Coordinator
Address: 3000 Pacific Ave SE, Olympia, WA 98504
Email: rules@lcb.wa.gov
Fax: 360-664-9689
Other:
By (date) October 3, 2018

Assistance for persons with disabilities:

Contact Claris Nnanabu, ADA Coordinator, Human Resources
Phone: 360-664-1642
Fax: 360-664-9689
TTY: 7-1-1 or 1-800-833-6388
Email: Claris.Nnanabu@lcb.wa.gov
Other:
By (date) September 28, 2018

Purpose of the proposal and its anticipated effects, including any changes in existing rules: Changes to cannabis rules in Chapter 314-55 WAC as a result of legislation passed during the 2017 legislative session, as well as a number of clarifying, technical, and other needed changes identified by stakeholders and WSLCB staff.

Reasons supporting proposal: Rulemaking is necessary to ensure rules are consistent with changes to laws made by the Legislature during the 2017 Legislative Session in ESSB 5131, SB 5130, and HB 1250. Other technical, clarifying, and needed changes to rules identified by staff and stakeholders are addressed, incorporating the CR-101 filed as WSR 16-15-035 into this rulemaking. Other changes to cannabis rules needed as a result of changes to laws made in the 2017 legislative session (retail license forfeitures) is underway under a separate CR-102, and changes to advertising rules due to 2017 legislative changes to RCW 69.50.369 have already been completed under a separate rulemaking.

Statutory authority for adoption: ESSHB 2334 (SL 2018 c. 132), RCW 69.50.342, and RCW 69.50.345

Statute being implemented: ESSHB 2334 (SL 2018 c. 132), RCW 69.50.342, and RCW 69.50.345

Is rule necessary because of a:

- Federal Law? Yes No
Federal Court Decision? Yes No
State Court Decision? Yes No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

Name of proponent: (person or organization) Washington State Liquor and Cannabis Board Private
 Public
 Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting: Coordinator	Joanna Eide, Policy and Rules	3000 Pacific Ave SE, Olympia, WA 98504	360-664-1622
Implementation:	Chief Justin Nordhorn	3000 Pacific Ave SE, Olympia, WA 98504	360-664-1726
Enforcement:	Chief Justin Nordhorn	30000 Pacific Ave SE, Olympia, WA 98504	360-664-1726

Is a school district fiscal impact statement required under RCW 28A.305.135? Yes No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

- Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Is a cost-benefit analysis required under RCW 34.05.328?

- Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

No: Please explain: A cost benefit analysis was not required under RCW 34.05.325 because the subject of proposed rulemaking does not qualify as a significant legislative rule or other rule requiring a cost benefit analysis under RCW 34.05.328(5).

Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

- | | |
|---|---|
| <input type="checkbox"/> RCW 34.05.310 (4)(b)
(Internal government operations) | <input checked="" type="checkbox"/> RCW 34.05.310 (4)(e)
(Dictated by statute) |
| <input type="checkbox"/> RCW 34.05.310 (4)(c)
(Incorporation by reference) | <input checked="" type="checkbox"/> RCW 34.05.310 (4)(f)
(Set or adjust fees) |
| <input checked="" type="checkbox"/> RCW 34.05.310 (4)(d)
(Correct or clarify language) | <input checked="" type="checkbox"/> RCW 34.05.310 (4)(g)
((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit) |

This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of exemptions, if necessary: This rule proposal incorporates changes needed as a result of 2018 cannabis legislation. These proposed rules were directed to be created by the Legislature through statute changes or requested by the regulated industry. Changes to fees are set by statute and all other costs for compliance of any changes to recordkeeping, reporting, and other compliance requirements were determined to be minimal, similar to current requirements for cannabis already in place, and do not disproportionately impact small businesses. Further, these changes are needed to ensure proper regulation of a controlled substance under state and federal law and costs have been mitigated or reduced as much as possible under the circumstances.

COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES

If the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

No Briefly summarize the agency's analysis showing how costs were calculated. _____

Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

- Name:
- Address:
- Phone:
- Fax:
- TTY:
- Email:
- Other:

Date: August 22, 2018

Name: Jane Rushford

Title: Chair

Signature:



NEW SECTION

WAC 314-55-109 Cannabinoid additives—Requirements, restrictions, and quality assurance testing. (1) As provided in RCW 69.50.326 Licensed marijuana producers and licensed marijuana processors may use a cannabidiol (CBD) product obtained from a source not licensed under this chapter, provided the CBD product:

(a) Has a THC level of 0.3 percent or less; and
(b) Has been tested for contaminants and toxins by a testing laboratory accredited under this chapter and in accordance with testing standards established in this section.

(2) Licensed marijuana producers and licensed marijuana processors may use a CBD product obtained from a source not licensed under this chapter and chapter 69.50 RCW as an additive for the purpose of enhancing the CBD concentration of any product authorized for production, processing, and sale under this chapter. However, useable marijuana, except marijuana that is an intermediate product that will be converted into a marijuana-infused product or a marijuana concentrate, may not be treated or otherwise adulterated in any way including the addition of a CBD product consistent with the rules of this chapter. Except as allowed under this section, CBD product additives must be lawfully produced by, or purchased from, a producer or processor licensed under this chapter. The testing requirements for CBD products derived from marijuana produced by marijuana licensees are provided in WAC 314-55-102. The testing requirements in this section are required in addition to quality assurance testing otherwise required under this chapter for marijuana products.

(3) **Traceability requirements.** A licensee must enter CBD products obtained from a source not licensed under this chapter into the state traceability system and keep the information in the traceability system completely up to date, consistent with marijuana and marijuana product recordkeeping and traceability requirements in WAC 314-55-083. A licensee must keep CBD products obtained from a source not licensed under this chapter labeled and quarantined in an area separate from marijuana and marijuana products under video surveillance consistent with the requirements for controlled areas in WAC 314-55-083(3) until the CBD products successfully pass quality assurance testing or are destroyed due to failure of tests as provided in this section. At no time during the quarantine period can the product be handled or moved under any circumstances, except for purposes of deducting samples as required under this section, and is subject to auditing by the WSLCB or its designee(s). CBD products obtained from a source not licensed under this chapter that fail quality assurance testing as provided in this section must not be added to any marijuana product and must be disposed of consistent with WAC 314-55-097 and the disposal logged into the traceability system consistent with WAC 314-55-083.

(4) **Testing requirements.** The following sample deduction and testing requirements apply to CBD products obtained from a source not licensed under this chapter. Such products must successfully pass quality assurance testing prior to being added to any marijuana product. Samples that fail quality assurance testing and the corresponding products that the samples were deducted from must be disposed of consistent with WAC 314-55-097.

(a) **Sample size and deduction requirements.** Licensed producers, licensed processors, certified labs, and their employees must adhere

to the minimum sampling protocols as provided in this section. Samples must be deducted in a way that is most representative of the product the sample is deducted from. The minimum sample size for the testing requirements under this section for CBD products is one percent of the product as packaged by the manufacturer of the CBD product but in no case shall the sample be less than two grams. Licensees, certified labs, and their employees may not adulterate or change in any way the representative sample before the sample is tested.

(i) All samples must be collected/deducted in a sanitary environment using sanitary practices and ensure facilities are constructed, kept, and maintained in a clean and sanitary condition in accordance with rules and as prescribed by the Washington state department of agriculture under chapters 16-165 and 16-167 WAC.

(ii) Persons collecting samples must wash their hands prior to collecting a sample, wear appropriate gloves, and must use sanitary utensils and storage devices when collecting samples.

(iii) Samples must be placed in a sanitary plastic or glass container and stored in a location that prevents the propagation of pathogens and other contaminants, such as a secure, low-light, cool and dry location.

(iv) The licensee must maintain the CBD products from which the sample was deducted in a secure, low-light, cool, and dry location to prevent the products from becoming contaminated or degraded prior to the CBD products being added or incorporated into marijuana products after successful passage of testing requirements.

(v) Each quality assurance sample must be clearly marked "quality assurance sample" and be labeled with the following information:

(A) The unique identifier for the product generated by the state traceability system;

(B) The name of the certified lab receiving the sample;

(C) The license number and business or trade name of the licensee sending the sample;

(D) The date the sample was collected; and

(E) The weight of the sample.

(vi) Certified labs may retrieve samples from a marijuana licensee's licensed premises and transport the sample(s) directly to the lab. Certified labs may also return any unused portion of the sample(s).

(b) **Required fields of testing.**

(i) **Potency testing.** Potency testing is required to confirm the product is less than 0.3 percent THC, contains detectable levels of CBD, and to determine the levels of THC, THC-A, CBD, and CBD-A in the product. Synthetic cannabinoids as defined in RCW 69.50.204 are prohibited under RCW 69.50.401 and any test result that suggests the presence of a synthetic cannabinoid must be immediately reported to the WSLCB.

(A) Certified labs must test and report the following cannabinoids to the WSLCB in the state traceability system when testing for potency:

(I) THCA;

(II) THC;

(III) Total THC;

(IV) CBDA;

(V) CBD; and

(VI) Total CBD.

(B) Calculating total THC and total CBD.

(I) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA: $M \text{ total delta-9 THC} = M \text{ delta-9 THC} + (0.877 \times M \text{ delta-9 THCA})$.

(II) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: $M \text{ total CBD} = M \text{ CBD} + (0.877 \times M \text{ CBDA})$.

(C) Regardless of analytical equipment or methodology used for testing, certified labs must accurately measure and report the acidic (THCA and CBDA) and neutral (THC and CBD) forms of the cannabinoids.

(D) The following potency results fail quality assurance testing for the purposes of this section and the sample and corresponding product from which the sample was deducted must be disposed of consistent with this section and WAC 314-55-097:

(I) The CBD product tests above 0.3 percent THC;

(II) The CBD product does not contain any detectable amounts of CBD or CBD-A; and

(III) The sample test results indicate that a substance is present that is not THC, CBD, or inert substance which the THC or CBD is dissolved into.

(ii) **Pesticide screening.**

(A) Certified third-party labs must screen for any pesticides that are not allowed and are designated as having the potential for misuse on a list created, maintained, and periodically updated by the department of health in consultation with the Washington state department of agriculture and the WSLCB.

(B) If the WSLCB, WSDA, other designee of the WSLCB, or certified lab identifies a pesticide that is not allowed for use or application on marijuana under this chapter and is above the action levels provided in WAC 314-55-108, that sample and corresponding product from which the sample was deducted has failed quality assurance testing. A sample that tests at or above the action levels for pesticides consistent with WAC 314-55-108 fails pesticide testing requirements for the purposes of this section. A sample and corresponding product from which the sample was deducted that fails quality assurance testing under this section must be destroyed consistent with WAC 314-55-097.

(C) Certified third-party labs must also screen for pyrethrins and piperonyl butoxide (PBO) in samples of CBD products obtained from a source not licensed under this chapter. Certified third-party labs may also screen for additional pesticides not specifically required under this section and per the DOH list, however, any sample that tests at or above the action level for any pesticide(s) as established in WAC 314-55-108 fails the testing requirements under this section and must be disposed of consistent with WAC 314-55-097.

(iii) **Heavy metal screening.** For the purposes of heavy metal screening, a sample fails quality assurance testing and must be disposed of consistent with WAC 314-55-097 if it meets or exceeds the following limits:

Metal	Limit, µg/daily dose (5 grams)
Inorganic arsenic	10.0
Cadmium	4.1
Lead	6.0
Mercury	2.0

(iv) **Residual solvents screening.** Certified labs must test for the solvents listed in the table below at a minimum. Except as otherwise provided in this subsection, a sample and corresponding product from which the sample was deducted fail quality assurance testing for residual solvents and must be disposed of consistent with WAC 314-55-097 if the results meet or exceed the limits provided in the table below. Residual solvent results of more than 5,000 ppm for class three solvents, 50 ppm for class two solvents, and 2 ppm for class one solvents as defined in *United States Pharmacopoeia, USP 30 Chemical Tests / <467> - Residual Solvents (USP <467>)* not listed in the table below fail quality assurance testing.

Solvent	ppm
Acetone	5,000
Benzene	2
Butanes	5,000
Cyclohexane	3,880
Chloroform	2
Dichloromethane	600
Ethyl acetate	5,000
Heptanes	5,000
Hexanes	290
Isopropanol (2-propanol)	5,000
Methanol	3,000
Pentanes	5,000
Propane	5,000
Toluene	890
Xylene*	2,170

* Usually 60% *m*-xylene, 14% *p*-xylene, 9% *o*-xylene with 17% ethyl benzene.

(v) **Microbiological screening.** The sample and corresponding product from which the sample was deducted fail quality assurance testing for microbiological screening and must be disposed of consistent with WAC 314-55-097 if the results exceed the following limits:

	Enterobacteria (bile-tolerant gram-negative bacteria)	<i>E. coli</i> (pathogenic strains) and <i>Salmonella spp.</i>
Unprocessed Plant Material	10 ⁴	Not detected in 1g
Extracted or Processed Botanical Product	10 ³	Not detected in 1g

(vi) **Mycotoxin screening.** The sample and corresponding product from which the sample was deducted fail quality assurance testing for mycotoxin screening and must be disposed of consistent with WAC 314-55-097 if the results exceed the following limits:

- (A) Total of Aflatoxin B1, B2, G1, G2: 20 µg/kg of substance; and
- (B) Ochratoxin A: 20 µg/kg of substance.

(5) **Test results reporting requirements.** Certified labs must report all test results as required by this section into the state

traceability system within twenty-four hours of completion of the tests.

(6) **Retesting.** At the request of the producer or processor, the WSLCB may authorize a retest to validate a failed test result on a case-by-case basis. All costs of the retest will be borne by the producer or the processor requesting the retest. Potency retesting will generally not be authorized.

(7) **Remediation.** Producers and processors may remediate failed products so long as the remediation method does not impart any toxic or deleterious substance to the CBD products obtained from a source outside the regulated system. Remediation solvents or methods used on the product must be disclosed to a licensed processor the producer or producer/processor transfers the products to; a licensed retailer carrying marijuana products derived from the remediated product; or consumer upon request. The product(s) the failed sample(s) were deducted from must be remediated using the same remediation technique. No remediated CBD products obtained from a source outside the regulated system may be sold, transported, or used in the processing of marijuana products until the completion and successful passage of quality assurance testing as required in this section.

(8) A licensee or certified lab that violates any of the provisions of this section is subject to disciplinary action, including possible summary suspension or revocation of the producer license, processor license, producer/processor license, or lab certification.