Chapter WAC 246-70 Medical Cannabis Product Compliance
July 18, 2024 Department of Health Rulemaking Workshop

Draft Language - Summary, Recommendations, & Discussion Prompts

This document accompanies draft rule language for this rule section.

WAC 246-70-050 Quality Assurance and Quality Control

(1) Lab Accreditation

- Clarify that labs must be accredited by WSDA (due to change in law) and must be certified by LCB per WAC 314-55-0995.

(2) Testing Interval

- Changes are meant to clarify language, provide more flexibility, and align with LCB rules.
- Flower and plant matter sampling allowed after harvesting instead of when harvested or placed into lots.
- Keep as is – products intended for retail sale as concentrates, extracts, or for use as an intermediate product, after extraction.
- Keep as is – cannabinoid products from non-LCB licensed source, prior to addition to any product.

Discussion:

Current rule says concentrates/extracts must be tested after extraction and hot samples must be destroyed and not processed into concentrate or extract.

- **We would like your feedback on stages of testing and product types specifically for heavy metals. Under (4) Heavy metal screening below, we will further discuss product types and threshold/action level requirements.**

(3) Sample size

- Changes to align with LCB's sample size requirements in WAC 314-55-101(2).
- Clarification that the more stringent rule must be followed. If LCB changes sample sizes to be more restrictive, this rule would refer to the LCB rule.
- Keep as is – 2 grams per batch of finished concentrates, extracts, or intermediate products.
- Keep as is – For a cannabinoid product obtained from a source not licensed by the WSLCB, 1% of the product as packaged by the manufacturer or 2 grams; whichever is greater.
- **We need to consider expanding this section based on Alliance feedback:**

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Discussion:

We would like feedback on lot sizes and sample requirements. We are considering whether to:

- **Adjust the maximum lot size to be no more than 25 lbs.**
- **Keep lot size at 50 lb max and increasing the sample size.**
- **Add requirements to ensure representative sampling and pros and cons of sample requirements.**

(4) Heavy metal screening

- Changes are intended to increase patient safety by establishing higher testing standards.
- Suggested language reduces action levels to closer align with other states and the USP guidance.
- We used United States Pharmacopeia 232 (USP 232) for guidance.
- Maximum Daily Intake Dose was increased from 5g/day to 10 g/day.
- We used separate data sets in USP 232 to create action levels for ingestible and non-ingestible products.

Discussion:

We would like your feedback on the following:

- **Should we identify clearly in different tables separate action levels for ingestible verses non-ingestible?**
- **Is there benefit to patient and product safety if final edibles infused with medical grade concentrates are also tested for heavy metals, which would reveal heavy metals in other ingredients?**
- **Should concentrates that fail heavy metal inhalable levels but pass ingestible levels be sold as "ingestion-only" concentrates?**

(5) Terpenes

- Draft language requires terpene testing when final potency testing for the product is required by the WSLCB.
- Keep as is – Terpenes added to useable cannabis prohibited; Naturally occurring terpenes and terpenes generally recognized as safe by FDA (21 C.F.R., Chapter I, subchapter B).

Discussion:

- **What benefits, barriers, and outcomes may arise if adding terpene testing as a requirement for when final potency testing is completed? If required, should certain terpenes be tested.**
- **When should terpene testing be required for edibles and topicals?**
- **Should terpene concentration be limited to 10% in cannabis products? Should this limit include topicals?**

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(6) Pesticide, mycotoxin, microbiological, solvent screening.

- Draft language aligns these contaminant testing requirements with LCB requirements in WAC 314-55-102 and WAC 314-55-108.

Discussion:

- **What do you think of aligning this testing with LCB's rules and consider changes here in the future rulemaking?**

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Recommendations we received and rationale for not including at this time

Recommendation	DOH Response
Protocols for 3rd - party sampling, which parameters should be decided by the lab; how to handle affidavits. Examples: • Lab testing – if lab subcontracts some of the testing, contracted lab must append its results to the COA. • COA – Compliant logo must appear on the lab-provided COA. • COA – Must be provided to retailer. • COA – Must be available to consumer via QR code. • COA – Add requirements for security features. • COA – Require one-year expiration date (to protect if LCB changes this requirement).	We think this is outside of DOH scope of rulemaking DOH rulemaking authority: **RCW** 69.50.375(4) doesn't authorize us to regulate this.
Sample collection protocols • Collected by lab or "other certified party" • Collected in presence of licensee/designee • Collected under licensee's cameras AND • All sign attestation on method, time, location.	We think this is outside of DOH scope of rulemaking DOH rulemaking authority: **RCW** 69.50.375(4) doesn't authorize us to regulate this.
SOP Requirements • Sampler must not hold P/P/Retailer license. • Sampler must be part of entity authorized by LCB to transport. • Qualifications of samplers to be determined by DOH. • Sampler must have SOP (methods for representative sampling) approved by DOH. • Sampler must have SOP on hand during sampling.	We think this is outside of DOH scope of rulemaking DOH rulemaking authority: **RCW** 69.50.375(4) doesn't authorize us to regulate this.
Chain of Custody (COC) Requirements • Sampler develops/uses COC approved by DOH, as part of annual WSDA lab accreditation (ensure integrity of COC documentation).	We think this is outside of DOH scope of rulemaking DOH rulemaking authority:

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- Sampler must use COC form – includes 10 specific fields: names, signatures, dates, contact info, batch/lot #, matrix, size/weight, enviro conditions, etc.
  - Form also documents movement between licensees and transporters and cannot be altered once samples change hands.

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RCW 69.50.375(4) doesn't authorize us to regulate this.

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Batch Sampling:

Adopt additional, scaled sampling requirements based on batch size, up to batch size of 150,000 units.

Product Batch Size	Minimum Number of subsamples per sample
Less than 50 units	2 units
51-150 units	3 units
151-500 units	5 units
501-1,200 units	8 units

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We recommend keeping the 2 gram minimum for this rulemaking, and could consider changes in future rulemaking.

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Remove uniconazole and chlormequat chloride from testing list.

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These were only identified through our website, and not in rule (current rule gave us authority to identify pesticides for testing prior to LCB Pesticides rulemaking). We have since removed that list.

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Failed pesticide tests – clarify remediation is allowed per WAC 314-55-102(c)

Products that have failed pesticide testing may be remediated in accordance with the rules established in WAC 314-55-102 6 (a) through (C)(i).

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LCB says remediation is not allowed:

WAC 314-55-102(6)(c): (c) Remediation. Remediation is a process or technique applied to quantities of cannabis flower, lots, or batches. Remediation may occur after the first failure, depending on the failure, or if a retest process results in a second failure. Pesticide failures may not be remediated.

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Pyrethrin/piperonyl butoxide – there is a restriction that these cannot be applied to a plant less than 7 days before harvest; increase requirement to 20 days.

(e) Pesticides containing allowed pyrethrins or piperonyl butoxide (PBO) may not be applied less than seven twenty days prior to harvest.

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This is old language was established prior to LCB's pesticide rules. We recommend focusing on action levels to set higher standards for medical-grade product. Future rulemaking could consider more stringent action levels for pesticides.

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Hydrocarbon solvent residuals – lower AL to 500ppm.

(3) Residual Solvents. A sample and the related population fails quality control testing for residual

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We would need more evidence-based justification for decreasing AL for hydrocarbon solvent residuals.

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solvents if the results exceed the limits provided in the table below 500 pp, or, 50 ppm for class two solvents, and 2 ppm for any class one solvents as defined in United States Pharmacopoeia USP 30 Chemical Tests / <467> -	We referenced Oregon Health Authority's Technical Report on contaminant testing and action levels (based on USP 467 on hydrocarbon ALs).