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

Summary of Feedback from Participants

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.

- No comments.

(2) Testing Interval

- There was strong support for end product testing instead of intermediate testing. Since LCB requires end product testing for potency, this is an opportunity to build in sample requirements for heavy metal and terpene testing at this stage.
- DOH received input about sample size options for end products and will revisit that for a 2nd draft.
- ***We would like additional recommendations about how to approach end product testing for various product types.***

(3) Sample size

- Participants request that this be streamlined as possible.

  - Aligning DOH sampling amounts with LCB's can achieve this.

- It is also necessary to be protective of patient health as practicable.

  - Capping lots at 25 lbs and lowering ALs based on current health data may achieve this. Strains grown weighing over 25 lbs may be divided into two separate lots and would require 2 samples submitted for compliance testing, resulting in more product being tested for safety.

- 25 lb max lot size makes sense; this is half of what LCB currently allows.
- 25 lb max lot size – there was concern this may put disproportionate costs on small scale farmers.
  - Small scale farmers are likely producing smaller lots (25 lb or less), so would not see increased costs within this lot size threshold. Large-scale farmers that can produce lots over 25 lbs would bear additional cost since testing costs double for lots over 25 lbs.
- Edibles sample sizes are missing (related to above – testing interval).

  - We will revisit this as we consider end product testing requirements.

WAC 246-70-050 Quality Assurance and Quality Control – Summary of Feedback

- There was discussion about whether increased sample sizes make contaminants easier vs more difficult to detect. Conclusion that increased sample sizes result in better detection of contaminants.

(4) Heavy metal screening

- Feedback that separate action level (AL) tables for inhalable vs. ingestible route of administration makes sense. But we need terminology that matches LCB product types (rather than ingestible/non-ingestible – this creates confusion when some consider smoking "ingesting"…)

  - The intention of the inhalable/ingestible distinction is to identify whether the product passes through the liver or bypasses first-pass metabolism.

  - DOH will develop language/definitions linking separate table to LCB end product types:

    "*Ingestible products*" include infused solid edibles and infused liquid (like a soda or tonic).

    "*Noningestible products*" include infused topicals, cannabis mix packaged (loose or rolled), cannabis mix infused (loose or rolled), and concentrates or cannabis-infused products for inhalation."

- Request not to put the 10 g permissible daily dose in rule language; it makes sense to use as a reference for the AL tables but is not appropriate for regulation.

  - DOH will remove this reference in rule language, but this number is still needed as a denominator for relative Daily Dose Permissible Exposure limits. For example: Per USP <232>, the Inhalation Daily Dose PDE for cadmium is 2 µg per day. DOH could allow for 2 µg cadmium per 5 grams of product or per 10 grams of product; the latter having a lower AL (more stringent requirement).

- All proposed ALs are lower than current ALs except for ingested mercury (which has been well studied in the consumption of fish).
  - We would like your feedback on whether the mercury ALs should be more stringent.

- There was discussion about whether the liver process heavy metals like other contaminants. The following resources were shared in the chat to confirm this:

  Heavy Metal Toxicity – StatPearls – NCBI Bookshelf (nih.gov)

  Heavy Metal Poisoning (Heavy Metal Toxicity): Symptoms, Causes & Treatment (clevelandclinic.org)

(5) Terpenes

- There was a question of whether there is a WSDA accreditation requirement for labs to test for terpenes.

  - Terpenes would currently be categorized by WAC 16-309-230 "Other analytes".

  - Should DOH require terpene testing, it is within the scope of WSDA/CLASP to determine the accreditation requirements and approved methods.

- Concern about efficacy, purported health benefits; what about other compounds (i.e. flavonoids).
- There was concern that therapeutic benefits evidence is lacking.

  - Testing would not be to claim a therapeutic claim but would give patient information to make a decision about benefit for their condition.

WAC 246-70-050 Quality Assurance and Quality Control – Summary of Feedback

- There is a high demand for terpene information; patients rely on this. It's a big marker for DOH medically compliant vs. recreational.

- Where to draw line? List terpene info without claims to therapeutic effects. List top 3 on label.

- Participants reiterated that including QR code to the COA would resolve many issues for patients.

  - Packaging can list the top 3 terpenes; QR code can list the rest, if any.

- Concern was expressed about adverse reactions to some terpenes.

  - This would suggest more reason to perform terpene testing.

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

- General agreement to focus on changes for other sections and consider higher standards for contaminants under (6) in a later rulemaking.

Other comments:

- The job aid/testing flowchart tool was very helpful. Can this be made available to the public?

- There was concern that test result may not be available to the retailer.

  - Test results must be made available to retailer WAC 314-55-075(11).

- DOH needs to consult with AAG about rulemaking authority regarding COAs. If DOH doesn't have authority, who does?

  - We will look into this!

WAC 246-70-050 Quality Assurance and Quality Control – Summary of Feedback

Recommendations we received and rationale for not including at this time

- ***We will revisit some of these recommendations based on workshop feedback***

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:

WAC 246-70-050 Quality Assurance and Quality Control – Summary of Feedback

<table>
<tr>
<td>

- 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.

</td>
<td>

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

</td>
</tr>
<tr>
<td>

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

...

</td>
<td>

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

</td>
</tr>
<tr>
<td>

Remove uniconazole and chlormequat chloride from testing list.

</td>
<td>

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.

</td>
</tr>
<tr>
<td>

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).

</td>
<td>

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.

</td>
</tr>
<tr>
<td>

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.

</td>
<td>

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.

</td>
</tr>
<tr>
<td>

Hydrocarbon solvent residuals – lower AL to 500ppm.

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

</td>
<td>

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

</td>
</tr>
</table>

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).