Significant Legislative Rule Analysis

Chapter 314-55 Rules Concerning Marijuana Quality Assurance and Quality Control Testing

December 8, 2021

SECTON 1:

Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

These proposed rule amendments revise and update marijuana quality assurance sampling protocols described in WAC 314-55-101, marijuana quality assurance and control described in WAC 314-55-102, and marijuana proficiency testing described in WAC 314-55-1025.

The purpose of the proposed rules is to require that all marijuana products produced and sold in Washington State are tested for pesticides. The proposed rules also allow the Washington State Liquor and Cannabis Board (WSLCB) to conduct randomized or investigation driven testing for heavy metals in marijuana products. It is anticipated that the effect of these rules will be to promote the overarching goal of the WSLCB to protect public health and safety, and to assure that all products sold within the I-502 market are safe for all consumers.

Proposed changes to existing rules include:

- Revised sample collection and storage procedures;
- Increasing the maximum amount of marijuana flower that may be represented by a single I-502 panel of tests and revising the number of one-gram flower samples required for testing;
- Elimination of the ability of certified labs to return unused portions of samples to licensees;
- Revised guidance to labs regarding when to reject or fail a sample;
- Updated lab testing requirements and procedures;
- Updated and expanded information regarding testing levels for water activity, potency analysis, foreign matter inspection, microbial screening, mycotoxin screening, and residual solvent screening;
- Addition of required pesticide screening and randomized or investigation driven testing for heavy metals;
- Updated rule language regarding product retesting, remediation of failed lots, and referencing of samples; and
- Updated reporting requirements for lab proficiency testing.

The proposed rule also renames and more appropriately refers to marijuana *quality control* sampling protocols and marijuana *quality control* and assurance testing standards. While quality control is a set of activities designed to evaluate a product, quality assurance pertains to activities that are designed to ensure that a *process* is adequate and the system meets its objectives. In contrast, quality control focuses on finding defects or anomalies in a product or deliverable, and checks whether defined requirements are met. Testing is one example of a quality control activity, but there are many more such activities that make up quality control. For these reasons, this proposal renames these sections.

Other proposed revisions include streamlined, clarified language, and section reorganization to increase readability.

Background

In 2012, Washington State voters approved Initiative 502 (I-502) that created a "tightly regulated" system for the production, processing, and distribution of marijuana for adult use by those 21 years of age and older. The WSLCB was tasked with creating the licensing and enforcement frameworks for such a system, assuring that each of these structures supported an overarching agency goal of ensuring the highest level of public safety.

RCW 69.50.348(1) provides that on a schedule determined by the WSLCB, every licensed marijuana producer and processor must submit representative samples of marijuana, usable marijuana, or marijuana infused *products* produced or processed by the licensee to an independent, third-party testing laboratory meeting the accreditation requirements established by the WSLCB for inspection and testing to certify compliance with standards adopted by the WSLCB. The provisions regarding accreditation will likely change on July 1, 2024, when third-party testing laboratories must meet new accreditation standards. However, most other elements regarding regulation of the *product,* including product testing standards, will remain the same. These elements include the following:

- Licensees submit the results of inspection and testing for quality assurance and quality control standards required under this section to the WSLCB on a form developed by the state liquor and cannabis board.
- If a sample inspected and tested under this section does not meet the applicable quality assurance and product standards established by the WSLCB, the entire lot from which the sample was taken must be remediated, or in the case of a failure for pesticides, the entire quantity must be destroyed.
- The WSLCB may adopt rules necessary to implement this section.

During the 2015 legislative session, the Cannabis Patient Protection Act (Senate Bill 5052) was introduced and adopted, creating a regulatory structure for the medical use of marijuana. Although this use had been permitted since 1998, the marijuana produced by individuals and under collective garden systems was not subject to the same testing and production standards as the newly established adult use market. Intended as a "…comprehensive act that uses the regulations in place for the recreational market to provide regulation for the medical use of marijuana," the bill placed the authority to establish standards around product testing for "medically compliant" product with the Department of Health (DOH).

Specifically, the bill noted that the legislature, "...intends that medical specific regulations be adopted as needed and under consultation of the departments of health and agriculture so that safe handling practices will be adopted and so that testing

standards for medical products meet or exceed those standards in use in the recreational market." The enacted amendments authorized WSLCB to determine approved pesticides and pesticide testing requirements, and required DOH to adopt rules related to products sold by licensed retailers holding a medical marijuana endorsement, including but not limited to pesticide testing requirements.

In 2016, the LCB formed a work group to reexamine marijuana quality assurance testing rules described in WAC 314-55-102, including but not limited to testing limits for residual solvents and microbial testing. Four meetings were held in 2016: April 28th, May 11th, June 7th, and July 1st. The work group consisted of 29 members (11 industry, 18 state agency and vendors, and 18 reviewers.)

Subsequently, the WSLCB adopted rules in 2016 related to sampling protocols under WAC 314-55-101, and amended portions of WAC 314-55-102 related to quality assurance testing. Substantial amendments to both regulations occurred in 2017, and more specifically, to WAC 314-55-102, adding a new section (2) clearly describing minimum required testing for each product type. Because DOH had adopted rules related to medically compliant products under WAC 246-70-050, requiring both heavy metal and pesticide screening for medically compliant products, *the WSLCB made these tests optional for adult use marijuana products at that time, based largely on industry concern that the costs of adding pesticide and heavy metals testing would reduce business viability.* Licensees producing and processing adult use marijuana products are not precluded or prevented from requesting pesticide and heavy metals testing for recreational product in addition to the basic suite of required I-502 tests.

Current Landscape

In early 2018, several stakeholders, including medical marijuana patients, consumers, and licensees, urged WSLCB to require producers and processors to test recreational crops for pesticides and heavy metals. These partners asserted that such a move, already adopted in other states, would inspire confidence among consumers, increase access to medically compliant products, and bolster sales. In August 2018, the WSLCB began the initial stages of rule development regarding marijuana quality control and product requirements. Among the rule changes being considered were whether all marijuana products be tested for pesticides and heavy metals.

The purpose of these proposed rules is to require that all marijuana products produced and sold in Washington State are tested for pesticides. The proposed rules also allow the WSLCB to conduct randomized or investigation driven testing for heavy metals in marijuana products. In order to meet potential demand for pesticide testing, there are currently a total of five marijuana testing labs in Washington State capable of testing for the full suite of I-502 tests, along with pesticides.

Licensees are responsible for selecting and implementing their own business models, and as a result, marijuana grows operate with a wide spectrum of growing techniques. Some grows are tightly controlled in indoor facilities; plants are grown in climatecontrolled chambers where every aspect of the plant's cultivation is monitored. Other grows are situated in outdoor environments dependent on seasonal cycles. While the variety of tests an accredited marijuana testing laboratory offers is entirely a business decision of the laboratory, many marijuana businesses are unable to select growing method based on a number of factors, including but not limited to access to capital, race, and gender. These disparities present significant challenges to licensees seeking to participate in the regulated marijuana market.

Marijuana cultivation, both indoor and outdoor, is associated with a variety of pests, bacteria, and fungi. Producers have used a wide variety of pesticides to reduce insect infestation. Pesticide misuse poses serious health risks to consumers, and exposure can result in a variety of well-document symptoms, such as difficulty breathing, abdominal pain, vomiting, dizziness, and muscle cramps. Additionally, some pesticides have been found to be carcinogenic (Taylor & Birkett, 2019).

Emerging literature and multiple studies, both nationally and globally, indicate that marijuana and marijuana products can become contaminated and must be tested to protect public health (Feldman, 2015; Subritzky, Pettigrew & Lenton, 2017; Feldman, 2015; Craven et. al., 2019; Seltenrich, 2019). Marijuana and its products can be contaminated with microbiological contaminants, such as mold or salmonella, potentially hazardous growth enhancers, and heavy metals such as chromium and lead. While marijuana in any form may be prone to contaminants will become concentrates may present a greater risk because any contaminants will become concentrated during processing (Seltenrich, 2019). To protect consumers against exposure to pesticides, solvents, and other contaminants, marijuana and marijuana products must be tested to ensure they are safe for consumption.

Current testing requirements for adult use marijuana are intended to ensure that products for sale are safe and have accurate potency levels. However, Washington state adult use marijuana products are not currently required to be tested for pesticides. Although not prevented from doing so, many producers and processors do not test for pesticides, and Washington is the only state that does not require this testing. Based on a number of elements, including consumer concern and national best practices, it is evident that standardized testing for all marijuana products produced, processed, and sold in Washington State is necessary.

There is no product testing guidance available to the WSLCB or any other state agency regulating marijuana from federal agencies who set standards for agriculture, food, and other products because marijuana remains classified as a Schedule I drug, and federally illegal. This presents regulatory challenges to the WSLCB, regulators throughout the country, and the industry since there is limited funding to support research on how marijuana tainted with potential toxins affects humans. However, while the possible health impact of consuming marijuana products with unapproved pesticides is an emerging area of research, the overarching goal of the WSLCB is to protect public health and safety, and to assure that all products sold within the I-502 market are safe for all consumers.

SECTION 2:

Is a Significant Analysis required for this rule?

Under RCW 34.05.328(5)(a)(i), the WSLCB is not required to complete a significant analysis for this or any of its rules. However, RCW 34.05.328(5)(a)(ii) also provides that except as provided by applicable statute, significant analysis applies to any rule of any agency, if voluntarily made applicable by the agency.

The WSLCB voluntarily asserts that the proposed amendments to WAC 314-55-101 and WAC 314-55-102 meet the definition of legislatively significant as described in RCW 34.05.328(5)(c)(iii)(C) because they are rules other than procedural or interpretive rules that adopt new, or make significant amendments to, a policy or regulatory program.

For these reasons, the WSLCB voluntarily offers this significant analysis.

SECTION 3:

Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The proposed rules implement chapters 69.50 and 69.51A RCW. These chapters codified Initiative 502 (2013), known as I-502, and Second Substitute Senate Bill 5052 (Chapter 70, Laws of 2015), known as 2SSB 5052.

The stated objective of I-502 was to "stop treating adult marijuana use as a crime and try a new approach" to achieve three specific goals, one of which was to bring marijuana into a tightly regulated, state-licensed system similar to that for controlling alcohol.

Similarly, the stated objective of 2SSB 5052 was to regulate the use of medical marijuana, to achieve three specific goals, one of which was to establish consistent testing, labeling, and product standards.

The proposed rules implement the goals and objectives of chapters 69.50 and 69.51A RCW by revising and updating product standards for marijuana products produced, processed, and sold within the regulated Washington State system.

SECTION 4:

Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

The proposed rules realize and embody the intent I-502 and 2SSB 5052 by establishing appropriate, uniform marijuana product standards to assure all products available at retail are safe for human consumption, and that those products meet or exceed product purity standards. The proposed rules supplement the existing product standards for adult use marijuana products by requiring all marijuana products produced, processed, and sold in Washington State to be tested for pesticides, assuring quality and purity standardization of all marijuana products available to Washington State consumers.

Rules are needed to establish enforceable standards for processors and producers, and assure that marijuana testing labs are aligned with and understand product standards and testing requirements.

SECTION 5:

Explain how the agency determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The proposed rules directly apply to licensed processors and producers who will bear the costs of additional testing requirements. Ultimately, however, consumers will bear the cost of these additional tests.

The proposed rules indirectly apply to accredited testing laboratories who will charge for, and conduct, testing of marijuana products.

It is important to note the distinction in the applicability of these proposed rules. The proposed rules do not change or alter the laboratory accreditation process, or revise any testing method development or validation processes labs may currently have in place. Marijuana testing labs in Washington State use varying business operating models, and each lab is responsible for, and independently choses, its own business model. While the proposed rules increase the required testing for marijuana products, they do not *require* testing labs to offer the full suite of tests. Marijuana testing labs have the *option* to offer all tests under the proposed rules. However, at this time, since the WSLCB's authority to regulate labs is limited solely to accreditation, whether or not labs offer all tests as proposed in these rules is a business decision borne solely by each lab, regardless of which agency administers an accreditation program.

Comparatively, the proposed rules will change marijuana product testing requirements as they apply to licensed processors and producers. As a result, the proposed rules are anticipated to have an initial cost impact on existing licensed processors and producers.

1. WAC 314-55-101 – Quality control sampling (formerly Quality assurance testing protocols)

Description of the proposed rule:

Originally entitled, "Quality assurance sampling protocols," this section has been renamed "Quality control sampling." This section describes how licensees collect samples of marijuana, usable marijuana, or marijuana infused products produced or processed by the licensee to accredited, independent third-party laboratories for inspection and testing to certify compliance with product quality control standards established by the WSLCB, consistent with RCW 69.50.348.

The proposed language has been updated and redesigned to increase readability, flow, and provide clarification, and because WAC 314-55-101 and WAC 314-55-102 are closely related, the WSLCB offers this analysis to transparently discuss and memorialize the agency's reasoning on these proposed amendments.

Proposed revisions include:

- Clarifying current language around sample collection, storage, labelling, and transportation for product quality control;
- Clearly stating under what circumstances a lab must reject or fail a sample; and
- Increasing the maximum amount of marijuana flower that may be represented by a single I-502 panel of tests to up to fifty pounds based on a graduated scale; and
- Specifying the number of one-gram flower samples required for testing larger quantities of marijuana flower.

Certified labs may still retrieve samples from a marijuana licensee's premise and transport those samples. Labs may no longer return any unused portion of the samples, and the proposal requires that labs must also destroy any unused portion of the samples as well. Additionally, language regarding sampling has been updated, simplified, and reorganized without substantive impact on current requirements.

Cost/Benefit Analysis:

The proposed rules reaffirm existing sample collection protocols designed to reduce product contamination during and after sample collection.

The proposal increases the maximum amount of marijuana flower that may be represented by a single I-502 panel of tests. No verifiable evidence or data was submitted to support the idea that a representative sample could be realized in larger lot sizes without increasing the number of samples, nor was there any consensus between any of the commenters regarding lot size before, during, or after these Listen and Learn session.

From one perspective, larger lot size eases regulatory burden and cost. Since sampled material cannot be sold, a large lot size decreases loss of unsellable marijuana. However, if there is a large amount of variation within an individual lot, and this is common with marijuana, a sample from within that lot might have drastically different properties than another part of the lot. If the sample does not pass testing requirements, then the entire lot must be destroyed, meaning that in the case of a fifty-pound lot, loss of the entire lot. While some large producers would be able to absorb this loss and remain viable, the same would not be true for other licensees subject to these rules.

Since marijuana is a highly variable crop, the lot size must recognize the unique makeup of a particular harvest. This adjusted lot size attempts to recognize the unique makeup of each harvest, while attempting to reduce variability, cost of testing, and potential loss across all tiers. However, collecting the correct amount and quality of product sample remains the responsibility of the licensee.

Under this proposal, sampling frequency may decrease, offering a cost reduction and an additional pathway to compliance. Licensees have the option to sample a lot of marijuana flower weighing up to fifty pounds for testing, but also may continue current practices since they are not precluded from continuing to sample five pound lots if this best fits their business model. This offers flexibility to adjust sample size to individual business model.

2. WAC 314-55-102 – Quality assurance and quality control (formerly Quality assurance testing)

Description of the proposed rule:

Originally entitled, "Quality assurance testing," this section has been renamed "Quality assurance and quality control." Previously, required quality control tests included five tests – moisture analysis, potency analysis, foreign matter screening, microbiological screening, and mycotoxin screening for most products. The proposed rules reaffirm these required tests, and add testing for pesticides. The proposed rule also allows the WSLCB to conduct randomized or investigation driven testing for heavy metals. Other changes to existing rules include updated and expanded information regarding testing levels and updated rule language regarding product retesting, remediation of failed lots, and referencing of samples to other labs for pesticide, mycotoxin, and optional heavy metal testing.

The WSLCB contracted with Industrial Economics through the Governor's Office of Regulatory Innovation and Assistance (ORIA) in mid-2021 to perform a small business economic impact statement (SBEIS) under the framework of chapter 19.85 RCW for this particular section of rule. The SBEIS was drafted based on draft conceptual rules as well as on the best publicly available data at the time, and considers lot size increase and other revisions proposed in the CR 102. The best analogous industry types and

associated NAICS coding as of November, 2021 have been used for the calculations, and the SBEIS analyzes the rule proposal.

It is critical to understand the differences between what an SBEIS does and is required for, and what a cost/benefit analysis does and is required for under RCW 34.05.328. The WSLCB intends to provide educational opportunities to interested parties regarding each of the processes and their very different purposes in the future. The WSLCB encourages interested parties to review <u>ORIA's frequently asked questions</u> regarding SBEIS and significant analysis.

<u>Analysis</u>

A key objective of regulating marijuana is ensuring that products sold at retail are as safe as possible for consumption (Pacula, Kilmer, Wagenaar, Chaloupka & Caulkins, 2014). The use of pesticides on marijuana crops is a complex and often confusing issue for a range of stakeholders, including cultivators, regulators, retailers, labs, consumers, and public health researchers. While marijuana growers are interested in pest management to defend crops (referring to pest in the broadest sense), invertebrates, weeds, pathogens, and insects, regulators are concerned with pesticide management and reducing potential for risk to public health, particularly consumers and workers (Ehler, 2006). No pesticide is currently registered in the US specifically for marijuana (Stone, 2014; Thomas & ElSohly, 2016).

Like most crops grown in the United States, marijuana is vulnerable to pests. However, unlike most crops, the Environmental Protection agency (EPA) has not approved any pesticides for use on marijuana pants, and 28 U.S.C § 136j(a)(2)(G) dictates that a pesticide may not be used inconsistently with its labeling. Therefore, application of any pesticide not approved for general use on marijuana plants violates federal law. This leaves marijuana producers with the options of either (1) using no pesticides; (2) using pesticides that do not require EPA approval for use on crops; or (3) illegally using pesticides approved for other crops.

The toxicological effects of pesticides, heavy metals, mycotoxins, and pathogenic microbes is well-documented in literature, including their carcinogenicity, neurotoxicity, and teratogenicity (Bennett & Klich, 2003; Damalas & Eleftherohorinos, 2011; Denkhaus & Salnikow, 2002; Derbalah et al., 2019; Duruibe et al., 2007; Gargani et al.; 2011; Gud et al., 2018; Mostafalou & Abdollahi, 2013, 2017; Pham et al., 2010; Stone, 2014; Taylor et al., 1982; Ye et al, 2017). Exposure to these contaminants through consumption of marijuana products may lead to short- and long-term adverse effects. A number of pesticides have shown carcinogenic and mutagenic effects in humans and could be lethal when overdosed (Craven, Wawryk, Jiang, Liu & Li, 2019).

Of the 18 states that have legalized both medical and recreational marijuana, Washington is the only state that does not require pesticide and heavy metal testing for all product (Seltenrich, 2019; Taylor & Birkett, 2019; Feldman, 2015). Colorado, Oregon and California all require pesticide and heavy metal testing. States with only medical marijuana programs, such as Michigan, Rhode Island, and Maryland require testing for solvents, microbiological contaminants, as well as pesticides and heavy metals.

Currently, Washington marijuana testing requirements are more stringent for products identified as DOH compliant than they are for products considered adult use. While adult use and DOH compliant marijuana must be tested for microbiological contaminants, only DOH compliant product is tested for pesticides and heavy metals.

WSLCB must consider the implications for how the legal adult use marijuana market may best be regulated in the public health interest. From that perspective, the basic issue with substances or activities that may pose risk of harm is the need to limit harm (Room & Ornberg, 2019). Considering the various methods of marijuana consumption, marijuana treated with pesticides likely present more health hazards to consumers than food crops or tobacco. Both acute and long term exposure to certain contaminants can result in a range of adverse health effects.

For example,

- Exposure to the insecticide bifenthrin, which is part of the pyrethrinoid family, may be a carcinogen and ingestion can cause headaches, vomiting, and respiratory irritation.
- Exposure to pyrethrins can cause difficulty breathing, vomiting and diarrhea when inhaled, and over prolonged periods may cause tissue damage in respiratory passages, and tremors.
- Microbiological contaminants, such as salmonella, can cause serious infections in people with weakened immune systems.

The best way to avoid pesticide consumption would be to guarantee that pesticides are not on marijuana plants at all. Commercial growers abroad have grown marijuana in large quantities using "biocontrols" such as predatory insects and beneficial microorganisms. However, in the United States, marijuana cannot be classified as "organic" because the term is federally regulated, and the United States Department of Agriculture (USDA) does not recognize marijuana as a legal crop.

While the current rules represent the WSLCB's efforts to assure that marijuana testing factors in some of the known dangers of pesticides and solvents, the proposed rules add testing requirements for pesticides to protect public health and safety to the greatest extent possible. Existing language regarding remediation and retesting is reaffirmed and refined in the proposed rule text.

Cost/Benefit Analysis:

The WSLCB anticipates that these rules will not result in any additional administrative costs to licensees for the following reasons:

- Sampling practices and requirements are essentially the same. The WSLCB does not anticipate that these rules will result in additional employee time to deduct or handle samples;
- Administrative tasks, such as completing laboratory forms or documents, travel, or other costs associated with moving product to labs for testing are the same, and will not result in additional cost.

The WSLCB recognizes that these rules may result in additional operational costs to producers/processors, and has sought to mitigate those costs through increasing lot size, reducing the number of one-gram samples required for testing, and increasing the allowable canopy size for Tier 1 producers. However, product quality control testing is critical to ensuring that marijuana processed, produced, and sold in Washington State is free from harmful contaminants and safe for human consumption, regardless of the method by which that product is consumed.

As noted above, the use of pesticides on marijuana crops is complex, and no state "has it right" (Seltenrich, 2019). While producers are interested in pest management to defend crops (referring to pest in the widest sense as invertebrates, weeds, pathogens, and insects), regulators are interested in pesticide management and reducing possible risk to public health, and consumers in particular (Ehler, 2006; Subritzky, Pettigrew & Lenton, 2016). Also as noted above, no pesticide is currently registered in the US specifically for marijuana (Stone, 2014; Thomas & ElSohly, 2015). The WSLCB has an overarching responsibility to assure marijuana products are safe for human consumption. This proposal is a significant step toward assuring that all marijuana products produced and sold in Washington State meet stringent standards designed to protect the public health and safety.

More importantly, these revisions to quality control rules provide public benefit at a time when there are a wide variety of untested products both inside and outside the I-502 system. Assuring that all marijuana product aligns with stringent product quality standards supports efforts to increase consumer protection when it is most needed to align with ongoing statewide public safety and harm prevention efforts. WSLCB's mission is to promote public safety through trust and fair administration of enforcement of liquor, cannabis, tobacco, and vapor laws. This proposal not only promotes, but supports current public safety efforts by assuring that all product entering the I-502 marketplace is safe for human consumption when it is needed most. This greater public benefit of safe, appropriately tested marijuana product outweighs compliance costs.

SECTION 6:

Identify alternative versions of the rule that were considered, and explain how the agency determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

Rule Development and Stakeholder Engagement Process

The WSLCB's stakeholder engagement process encourages parties to:

- Identify burdensome areas of existing and proposed rules;
- Propose initial or draft rule changes; and
- Refine those changes.

Rule Project History

This project has a lengthy history of rule development and extensive stakeholder engagement. The first Listen and Learn session on draft conceptual rules was held in April 2019, and the second was held in August 2019. It is important to note that these two sessions on marijuana products were among the first that the WSLCB offered to increase and enrich stakeholder engagement in the rule development process.

Initially, and understandably, in person participation was somewhat guarded as the licensed community and others became familiar with the approach, and the concept of collaborative rule making. It is also important to note that few producers and processors attended the first meeting despite all licensees receiving notice of the meeting more than two weeks in advance. By the second session, attendees were better prepared to present and discuss ideas and solutions, and the conversation continued well beyond the scheduled session time, although again, few producers and processors attended in person even though messaging was broadly distributed to all licensees through several platforms. However, several of these entities provided written comments in the way of email to the rules coordinator during the meeting. These were shared at the meetings, and throughout the rule development process.

Additionally, agency staff visited the facilities of processors, producers, and labs who wished to participate in the process. To the extent possible, the qualitative and quantitative data presented in this significant analysis represent the multiple dimensions and broad spectrum of positions, as well as mitigation strategies offered by all participating parties. The WSLCB also coordinated rule development with staff the Washington State Department of Health, the Washington State Department of Ecology, and the Washington State Department of Agriculture where possible and appropriate.

Many of the comments received from licensees and labs focused on individual business viability. Very few comments received during the initial stakeholder engagement process prioritized public health and safety, concentrated on ways to increase product purity or consumer confidence, or tied the production of safe products to existing business models.

In contrast, the majority of the comments from consumers received after the CR101 was filed concentrated on a presumption of recreational product safety. For example,

"As a long time consumer, I was shocked to learn that pot is not tested for pesticides! I learned this from one of the budtenders I recently spoke to in Maple Valley, which was funny because every other budtender I've ever talked to has

sworn up and down that pot IS tested for pesticides. However, this budtender seemed incredibly well informed and assured me that no, pot is NOT tested for pesticides in Washington. I realize you guys probably have a lot to do and focus on, but this seems like a no brainer to me. Why wouldn't we require pot to be tested for pesticides? Considering we are concentrating the pot and then combusting it, literally changing the chemical make up of the flower, it seems irresponsible to not require pesticide testing in the legal market for all pot products. As a consumer I want to know that the product I'm purchasing is safe and thus pesticide testing seems immenat [sic]. Please do the right thing, make haste, and require mandatory pesticide testing for all legal pot products now!"

- Received in WSLCB rules in-box, September 14, 2018

In all, well over 350 comments were received, organized, and reviewed as part of initial development efforts. These became a part of the original CR 102 package for this project.

The Board approved the first CR 102 for this project on January 22, 2020, setting a public hearing for March 18, 2020. However, this hearing was continued based on the status of the COVID-19 outbreak and the agency transferring operations to an all-virtual and remote platform that at the time, did not offer a way to hold a public hearing. The hearing was continued, but as the pandemic surged, the Board withdrew the CR 102 on the premise that it would re-file once an appropriate platform was available. On May 27, 2020, the Board approved re-filing of the original CR 102, setting a hearing date for July 8, 2020.

The hearing was held on July 8, 2020, and based on substantive feedback resulting in substantive changes to the proposal, the Board approved a supplemental CR 102 on September 20, 2020 with a hearing date of November 18, 2020. Following this hearing, the Board reviewed all feedback, and determined that a new approach was necessary.

To assure that the agency understood and heard from the complete system – processors, producers, retailers, consumers, and others – and provide an opportunity for all in the supply chain to have an opportunity to hear the wide range of perspectives around product testing, the WSLCB hosted three Deliberative Dialogue sessions on marijuana product testing in January and February 2021. These sessions were used to inform the development of new draft conceptual rules.

Current Rule Proposal

A Listen and Learn session on the new draft conceptual rules on October 20, 2021. . These sessions were announced via GovDelivery and other media platforms, and open to the public, licensees, and any interested party to encourage community input. The WSLCB is aware that this is a topic of interest to many Washington State citizens, regardless of their positionality related to the regulatory structure. The WSLCB received a number of written and oral comments during and after the Listen and Learn session held on October 20, 2021 on a conceptual draft of this proposal. Comments continued to be offered through November 2021. These comments did not embody or represent broad licensee or lab agreement on any specific theme or themes. These comments concerned sample collection, lot size, increased cost to producers and processors, along with comments that did not pertain to this section of rule.

Organizing comments to provide brief descriptions of issues and themes related to the proposed rule set in this context continues to be challenging because of the number of comments collected as a result of the Listen and Learn session. These comments represent a broad range of opinions and positions, along with several suggestions regarding draft conceptual rules. As a result, thematic organization is difficult.

Agency staff worked to preserve comments in their native form to assure not only transparency, but to make sure that each commenter was offered the opportunity to review and digest comments and thoughts of the entire community in their native form, as opposed to a curated, summarized version of comments interpreted by the WSLCB. The WSLCB intends to continue sharing comments in their native form.

Some of the suggestions included rule changes that exceed the scope of the CR101 for this project, or internal operational changes that may exceed WSLCB available funding and capacity. Suggestions included the following examples:

- "With current pesticide testing I find that a product is tested way too many times. Processors want product tested, and then they test again. Right now this industry has adopted a very costly approach to testing, and this rulemaking seems to continue that trend. I really hope that we get pesticide testing that is not overly burdensome to farmers and protects consumers. Self selection testing at the lot level does not achieve this."
- "This was an unexpected, dramatic and seemingly arbitrary proposal in testing requirements. Labs currently test 6 grams out of every 2,240 grams sold (5lb lot). According to these conceptual rules, labs will still test 6 grams regardless if the lot is 2,240 grams (5 pounds) or nearly 22,400 grams (50 pound lot). Clearly, meaningfulness of the results from that single battery of tests significantly decreases as the lot size grows.

While we can appreciate a desire to decrease a financial burden on producers and processors, reducing the current testing frequency does not appear to coincide with LCB mandate of public safety. Current testing costs are minimal when compared to overall costs involved, e.g., 8 cents per gram at our facility per 5 pounds.

In addition, we are unaware of any grower or processor having indicated that current testing requirements are burdensome, either during the meeting or elsewhere. To the contrary, several comments by growers during the meeting indicated concern regarding decreasing validity with increasing lot sizes and corresponding risks involved with potential failures of larger lot sizes.

Accordingly, we agree with the commenters that support the current rules involving 5 pound lots. The pending economic impact analysis may indicate the costs involved in pesticide testing are onerous. If so, requirements should be addressed as a separate matter with larger lot sizes allowed for pesticide testing specifically, leaving other testing requirements at 5lbs."

- "The proposed rule change will also tend to push smaller growers toward unicropping (growing lower numbers of strains). That is not necessarily a good thing."
- "We grow 8 strains in a small room, and cannot afford to have 8 pesticide tests each harvest. I think pesticide testing should also be done randomly on samples obtained from retail stores."
- "We harvest one strain at a time and we pesticide every 5 pounds. It costs us less than a penny per gram for pesticide testing. At \$200 a pesticide test, for a five pound lot, which is the most expensive I've seen on lab websites (and you can usually get a better deal if you stick to one lab and don't have any analytes for them to analyze...ie pesticide free) that would be \$.088 per gram. Just throwing some numbers out there."
- "In that case we need 2 types of testing lots 5lb by strain for regular QC (no changes) And harvest level testing by crop for pesticides Follow up with random off the store shelves testing to keep it all honest."
- "Samples must be of roughly equal weight not less than one gram each. Each sample must be deducted from a harvest as defined in WAC 314-55-010(14). Why? Why do they need to NOT be less than 1 gram? That seems arbitrary. If you're sending in a lot of B buds, 1 gram bugs may not be a representative sample. Furthermore, I think it is important to include a timeline with the definition of harvest in WAC 314-55-010(14). Otherwise it's easy to say that a harvest could be 1 day or a month or a perpetual harvest means you only need one test."

- "For compliance I would say the board "shall" conduct rather than "may". I really think the board is obligated to conduct random investigation on a heavy metal screening. We must conduct random screening at the store level. So I would suggest changing may to must or shall."
- "Potency analysis isn't an accurate term. THC and CBD do not by themselves indicate potency to the consumer or patient. Cannabinoid concentration is a better, more accurate term. After all of this Delta 8 hoopla (that's a technical term), I think we have learned the importance of using the correct terminology. This is an opportunity to adjust our vernacular before it's a problem."
- "Pesticide failures may not be remediated. Why? This should be allowed with board approval as the science continues to evolve. At least give the option..."
- "If a failed quantity of marijuana is not remediated or reprocessed in any way, it cannot be retested. Any subsequent certificates of analysis produced without remediation or reprocessing of the failed quantity of marijuana will not supersede the original compliance testing certificate of analysis. Again why?"
- "I feel that (a) should be more clear and the industry should not have to go to the board for approval. Rule should clearly show when product is remediable."
- "I'd like to see some sort of synthetic testing added to quality assurance."
- "Please include a requirement for a unique Sample ID for every sample. A unique sample ID is absolutely necessary to identify all samples submitted to a lab."

<u>Comments Received During and After the Listen and Learn Session held October 20,</u> 2021

• See Attachment A.

Alternative Versions of the Rule and Least Burdensome Alternative

One versions of draft conceptual rules were offered for stakeholder comment at the Listen and Learn Session. Several stakeholders offered alternative language, or specific suggested revisions. Most comments were general concepts about rule revision rather than actual rule language, complaints regarding current rule, or assertions that WSLCB

failed to appropriately develop rules, draft and vet draft conceptual rules, research, or understand the issue. As noted above, most comments spoke to the perceived effect a rule revision would have on businesses.

Summarized below are brief descriptions of issues related to the proposed rule set and how the agency collaborated with stakeholders to mitigate potential burden associated with rule compliance:

Issue	Potential Burden	Mitigation Strategy
Lot size	Producer/Processor : General consensus that lot size increase would decrease burden and reduce costs; others asserted that lot size should remain the same to assure a truly representative sample.	Proposal to increase the maximum amount of marijuana flower that may be represented by a single I-502 panel of tests to fifty pounds, with the number of samples required based on the weight of the marijuana flower being tested
Addition of pesticide testing and random or investigation driven heavy metal testing to current suite of required I-502 tests	Producer/Processor : No consensus on whether this would increase or decrease burden. Some indicate, as they did in 2016, that additional tests will reduce business viability; others agreed that testing was necessary.	Proposal maintains addition of pesticide testing. Heavy metals testing will not be mandatory for adult use product, but WSLCB will conduct random heavy metal testing. Licensees have the option to test for heavy metals consistent with DOH compliant product standards.

SECTION 7:

Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take action that violates requirements of federal or state law.

SECTION 8:

Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

SECTION 9:

Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is

justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not differ from any applicable federal regulation or statute.

SECTION 10:

Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

The agency coordinated to the extent possible with the Department of Health, the Washington State Department of Ecology and the Washington State Department of Agriculture.

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