Significant Legislative Rule Analysis

Chapter 314-55
Rules Concerning Marijuana Quality Assurance
Testing and Product Requirements

September 30, 2020
Supplemental CR 102

SECTON 1:

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

These supplemental, proposed rule amendments revise and update current 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.

This proposal provides that as of August 2021, sample collection for flower lots would increase from five pounds to ten pounds. It also provides that in addition to the currently required suite of tests, all marijuana products produced, processed, and sold in Washington State be tested for pesticides as of August 2021, and heavy metals as of February 2022. If adopted, these revisions would be accomplished by revising and updating existing WAC 314-55-101 and WAC 314-55-102 by way of a phase-in plan, as follows:

- On August 1, 2021, WAC 314-55-101 would be repealed, and WAC 314-55-1011 would become effective, replacing the five pound lot size with a ten pound lot size.
- On August 1, 2021, WAC 314-55-102 would be repealed, and WAC 314-55-1021 would become effective until January 31, 2022, adding pesticide testing to the current suite of required product testing for all marijuana products produced and sold in Washington State.
- Finally, on January 31, 2022, WAC 314-55-1021 would be repealed, and effective February 1, 2022, WAC 314-55-1022 would become effective, requiring both pesticides *and* heavy metals to the current suite of required product testing for all marijuana products produced and sold in Washington State.

As a technical matter, this proposal 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 the right requirements. 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; section reorganization to increase readability, along with reduction and removal of passive language where appropriate.

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 recreational use by adults 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 accreditation standards established by the Washington State Department of Ecology. However, all other elements regarding regulation of the *product,* including product testing standards, will remain the same, and provide that:

- Licensees submit the results of inspection and testing for quality assurance and product standards required under this section to the WSLCB on a form developed by the state liquor and cannabis board.
- If a representative 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 destroyed.
- Any sample remaining after testing shall be destroyed by the laboratory or returned to the licensee submitting the sample.
- 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 recreational 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 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 recreational 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 recreational 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 was whether all marijuana products be tested for pesticides and heavy metals.

As of the time of this analysis, there is currently one marijuana testing lab in Washington State capable of testing products for the full suite of I-502 tests, along with pesticides and heavy metals. There are currently a total of five labs 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 on a wide spectrum of sophistication. Some grows are tightly controlled in technologically advanced indoor facilities; plants are grown in climate-controlled chambers where every aspect of the plant's cultivation is monitored. Other grows are comparatively "low tech," set outdoors and dependent on seasonable cycles. Which growth model a licensed producer choses – either indoors or outdoors – is entirely a business decision of the licensee. Similarly, the variety of tests

an accredited marijuana testing laboratory offers is entirely a business decision of the laboratory.

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 contamination, extracts and 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 recreational marijuana are intended to ensure that products for sale are safe and have accurate potency levels. However, Washington state recreational marijuana products are not required to be tested for pesticides and heavy metals, and although not precluded from doing so, many producers and processors do not test for either, 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 has become evident that standardized testing for *all* marijuana products produced, processed, and sold in Washington State is necessary.

There is no 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.

Recently, concern around the composition and safety of marijuana concentrates for inhalation has highlighted the need to assure that all marijuana products are tested for the presence of harmful compounds and other contaminants. The proposed rule amendments and phase-in plan offer a reasonable time frame that provides both

licensees and accredited labs the opportunity to adjust business models where necessary, and offers options to prepare for additional fields of testing either immediately or over an extended, but finite period of time.

Need for Supplemental Proposal

A public hearing was on the initial rule proposal for this project was held on July 8, 2020 consistent with WSR 20-12-026. After review of comments received, WSLCB made substantive revisions to the proposal that require an additional public hearing.

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 proposed new section WAC 314-55-1011, and WAC 314-55-102, and proposed new sections WAC 314-55-1021, and -1022 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.

The proposed amendments to WAC 314-55-1025 are exempt under RCW 34.05.328(5)(b)(iv) because they make changes and clarify language without changing rule effect.

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 standard 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 align the existing product standards for recreational and medically compliant marijuana products by supporting greater access to safe products for medically compromised consumers, while at the same time, 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 (formerly assurance) testing protocols, and WAC 314-55-1011 (Effective August 1, 2021).**

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 representative 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:

- Referring to "separate samples "as "subsamples;"
- Clarifying current language around retrieval and transportation for product quality control;
- Clarifying limitations on adulteration of product quality control samples that could circumvent contamination testing detection limits;
- Clearly stating under what circumstances a lab must reject or fail a sample; and
- Proposing to increase the sample collection for flower lot size from five pounds to ten pounds.

The WSLCB received a number of comments regarding current rule requirements, both in writing and orally, although these comments did not embody or represent broad licensee or lab agreement on any specific theme or themes. Comment regarding sampling protocol, lot size, increased cost to producers and processors, along with comments that did not pertain to this section of rule were gathered up to, during, and

after the first listen and learn session on April 9, 2019, the second listen and learn session on August 22, 2019 through the end of December, 2019. Comment on the rule proposal discussed at the public hearing on July 8, 2020 were also gathered and reviewed, resulting in this supplemental proposal.

As a result, the WSLCB maintained its original, proposed reorganized of this rule section, and in addition, proposes to increase the current minimum of four separate subsamples from each marijuana flower lot up to five pounds, to eight separate subsamples from each marijuana flower lot up to ten pounds on August 1, 2021 in conjunction with the addition of pesticide testing, and consistent with the phase in plan designed to implement these proposed rule revisions.

Certified labs may still retrieve samples from a marijuana licensee's premise and transport those samples. Labs may also continue to return any unused portion of the samples, and the proposal provides that labs may also destroy any unused portion of the samples, as well. Additionally, language regarding sampling and adulteration has been updated, simplified and reorganized without substantive impact on current requirements.

Cost/Benefit Analysis:

The proposed rules reaffirm existing sampling protocols designed to reduce, to the extent possible, product contamination during and after sample deduction.

The supplemental proposal increases the current sampling lot size from five pounds to ten pounds effective August 1, 2021. This increase in lot size is the triggering event for a supplemental proposal since this is a substantive change from the original proposal. The concept of expanding lot size to ten pounds or more was discussed during rule development and at both Listen and Learn sessions. 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 representative samples, nor was there any consensus between any of the commenters regarding lot size before, during, or after these Listen and Learn sessions.

WSLCB considered the several initial comments during rule development that Washington State consider regulatory frameworks similar to California and Oregon standards, including an increase from a 5 pound lot size to a 50 pound lot size. The WSLCB offers that in both Oregon and California, only labs deduct samples substantially increasing cost and regulatory oversight. In Washington, licensees may deduct samples, and normally do. Additionally, there are other differences in the statutory and regulatory structures between these states that do not align with the Washington State framework. In other words, practices in other states align with a system of regulation that is shared by multiple agencies and different licensing structures consistent with enabling legislation. In contrast, I-502 placed all authority for marijuana regulation with the WSLCB, a licensing and enforcement agency. It is not

possible to simply “lift and shift” another state’s regulatory structure for product quality control and place it in Washington’s framework.

For example, in California, all products must be first held by a *licensed distributor* – not the producer or processor - while they are tested by an independent, *licensed* laboratory. Licensed testing laboratories do not publish their prices, and the costs of testing services are not publicly available. Testing prices depend on the number of samples to be tested, the type of product testing, and the specifics of the contract between the distributor and the laboratory, among other factors. Similarly, Oregon labs perform every step of testing, including collecting and processing samples, performing compliance tests, and reporting results. Oregon also requires that, among other things, individuals performing “sampler” functions must be employed by an Oregon accredited laboratory, provide proof of training, and be licensed to transport required quantities of “usable marijuana items. These additional layers of regulatory oversight add significant cost to testing requirements and highlight the differences in enabling statute design.

While both California and Oregon allow larger batch weights or lot sizes, the sample increments for each lot or batch are proportionate and similar to Washington’s proposed requirements.

One of the few common themes emerging from comments received during the July 8, 2020 public hearing was a request to increase lot size to at least ten pounds or more. In considering this adjustment, the WSLCB analyzed the trade-off between accuracy (or representativeness) in testing results and compliance costs. 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 50 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 many licensees subject to these rules.

Since marijuana is a highly variable crop, the lot size must be small enough to 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 up to ten pounds, 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.

More importantly, these revisions to quality control rules provide public benefit at a time when public safety is not only critical, but necessary. As of September 25, 2020, the CoronaVirus Disease 2019, or COVID-19 respiratory illness has resulted in 2,175 deaths in Washington State alone, and over 200,000 deaths nationally. 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 reduction 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.

2. WAC 314-55-102 – Quality control (formerly assurance) testing; new sections WAC 314-55-1021 (Effective August 1, 2021 until January 31, 2022) and WAC 314-55-1022 (Effective February 1, 2022).

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 and heavy metals for all product types through an incremental phase-in plan. The proposed rule also provides that testing for terpene presence or concentration is required if a processor or producer indicates or states terpene content on any product packaging, labeling or both.

The WSLCB contracted with Industrial Economics through the Governor's Office of Regulatory Innovation and Assistance (ORIA) in early 2019 to perform a *preliminary* small business economic impact statement (SBEIS) under the framework of chapter 19.85 RCW for this particular section of rule. In most circumstances, the SBEIS is not completed until the actual rule proposal is prepared. In this instance, however, a preliminary SBEIS was prepared to serve solely as a basis to understand *estimated impact threshold only because data such as employment, revenue, and costs are not established in this particular industry as they are in other, more established industries.* The preliminary SBEIS was drafted based on draft conceptual rules offered in April 2019, as well as on the best publicly available data at the time, and updated to consider lot size increase proposed in the supplemental CR 102. The best analogous industry types and associated NAICS coding have been used to update calculations, and the updated SBEIS analyzes the supplemental 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 ORIA's frequently asked questions regarding SBEIS and significant analysis.

Analysis

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 or cannabis 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 cannabis (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 11 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 recreational. While recreational 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 recreational cannabis 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 then 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.
- Heavy metals, such as chromium may be carcinogenic to humans (Kim, Kim & Seo, 2015). Lead has been found in marijuana in tests performed in Germany and has no level of safe exposure. Heavy metals can affect the nervous system, cause kidney damage, slow brain development, and cause miscarriages. Arsenic is present in some groundwater sources and fertilizers that could be used on marijuana. Long-term exposure to arsenic can cause cancer and skin lesions, and acute exposure may cause vomiting, diarrhea, and even death.

Additionally, in 2016, the Association of Public Health Laboratories published a report for state medical marijuana testing programs that recommended testing for heavy metals in addition to solvents, pesticides, and micro biological contaminants. According to the report, heavy metals may accumulate in the body; some are carcinogenic, and considered to cause a variety of diseases. Marijuana is efficient at absorbing and storing heavy metals and other pollutants found in soil and water, which increases the risk that marijuana users could ingest or inhale heavy metals.

The best way to avoid pesticide and heavy metal 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 and heavy metals 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.

The proposed phase in plan for the addition of pesticides and heavy metals is provided as Attachment A to this significant analysis, and incorporated herein by reference. The proposed rules contemplate, and are written to support and control for this phase-in plan.

Cost/Benefit Analysis:

The WSLCB proposes to phase-in these requirements to provide additional time for impacted parties to adjust business models as needed. Attachment A provides a phase-in table. Attachment B describes estimated cost ranges if pesticide and heavy metals testing are added to the current suite of tests. Since this rule project began in August 2018, impacted parties have had in excess of two years to consider and prepare for this proposal. Under the proposed phase-in plan, licensees will have an additional extended period of time to adjust their self-selected business models.

The phase-in plan provides that upon the effective date of these proposed rules, should they be adopted, that existing levels of testing would remain the same, and only the technical revisions of the rule would go into immediate effect. At this time, the WSLCB anticipates a rule effective date of February 6, 2021. This would provide licensees six months after to prepare and adjust for the pesticide testing requirement and lot size increase, and for labs to prepare to offer the additional testing if they chose, with the pesticide testing requirement anticipated to go into effect on August 1, 2021. Then, licensees would have an additional six months to prepare for the addition of heavy metal testing, and it is anticipated that by February 1, 2022. There is currently more than one lab available and prepared to offer this testing, and it is anticipated that this number will increase by the final effective date.

As noted previously, the CR 101 was filed in this rule project in August of 2018, and it is anticipated that these proposed rules would be fully effective in February, 2022. Under that timeline, licensees will have had well over three years to adjust business models and plans in preparation for these rule revisions that align the state of Washington with national practice. 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 costs to producers/processors, and has sought to mitigate those costs through increasing lot

size and a phased in approach. 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 public safety is not only critical, but necessary. As of September 25, 2020, the CoronaVirus Disease 2019, or COVID-19 respiratory illness has resulted in 2,175 deaths in Washington State alone, and over 200,000 deaths nationally. 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 reduction 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

Virtually all of the comments received from licensees and labs focused on individual business viability. Fewer than five comments out of over 300 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*

The WSLCB's stakeholder engagement process encouraged parties to:

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

During the rule development process, the WSLCB hosted two public "Listen and Learn" sessions, and collected significant input from industry members, associations and other interested parties, representing processors and producers across tiers and many others. These meetings and comment periods 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.

It is important to note that these "Listen and Learn" sessions 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 comment 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.

Although summarizing comments to provide brief descriptions of issues and themes related to the proposed rule set in general practice, doing so in this context was extremely challenging because over 300 comments were collected as a result of the two Listen and Learn sessions, and throughout the rule development process. These comments represented an extremely broad, often conflicting range of opinions and positions, along with multiple suggestions regarding draft conceptual rules. As a result, thematic organization was virtually impossible.

Despite criticism that the comments were not distilled and summarized when initially publicly shared, 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, regardless of volume, moving forward.

Many of the suggestions offered required legislative or other action beyond the scope of the Board's regulatory authority. Other suggestions included creating new WSLCB programs, expanding on existing limited contracts, requesting rule changes that exceed the scope of the CR101 for this project, or suggesting internal operational changes that may exceed WSLCB available funding and capacity. Some of these suggestions included:

- WSLCB should create carve outs or exemptions from any additional product testing for Tier 1 producers and sun growers. Sampling frequency should be reduced for these Tier 1 producers.

- Sun growers should be "empowered" to select their own lot size. (Received December 29, 2019).

- Tier 1 exports of cannabis from Washington should be exempt from all cannabis sampling requirements. It was asserted that the receiving State or Country's testing requirements should dictate testing criteria.

- The WSLCB should immediately engage in emergency rulemaking for pesticide and heavy metal testing while simultaneously extending the period of the CR102, which at the time of the comment was not yet been presented to the Board or filed.

- The WSLCB should reduce the statutorily established tax rate on marijuana products from 37% to 20% to accommodate the increased cost of testing.

- The WSLCB should require the WSDA to perform 500 – 1000 random tests per month. WSLCB enforcement should collect random samples, and contract with "a lab for expanded testing."

- WSLCB should not require "cannabis farmers to significantly increase spending with Washington's cannabis labs until Washington State Department of Ecology accreditation is complete." (Received December 29, 2019)

- Enterobacteria testing should be changed to an indicator test instead of a pass-fail test with follow up testing for pathogens, if high levels of enterobacteria are found (Received December 29, 2019).

- The WSLCB should remove pyrethrins and piperonyl butoxide from the list of pesticides with action levels prior to implementing additional testing requirements. (Received December 29, 2019).

- The WSLCB should not remove pyrethins and piperonyl butoxide from the list of pesticides with action levels.

- The WSLCB should allow EPA Method 6200 to be self-performed at Tier 1 facilities for heavy metals compliance.

- The WSLCB should allow Tier 1 producers to combine samples and provide a single report for pesticide compliance. Tier 1 licensed farms would then be designated a quarantine facility and training developed to identify live pests and carcasses prior to combining samples. Tier 1 producers would be allowed to transport cannabis in Washington State prior to testing to accomplish this program.

- The WSLCB should allow Tier 1 producers to fundraise by selling directly to the public.

- Rather than adopt heavy metal testing, the WSLCB should develop a program to verify processors have the Material Safety Data Sheets (MSDS) for all raw materials used in their vape hardware and heavy metal testing results provided by their hardware distributor and/or manufacturer. WSLCB should perform random testing for heavy metals in vape cartridges. (Received December 29, 2019).

- Statistically representative samples should be taken from the lot for testing purposes and results should provide measures of variance so that potency can be reported and better represent the harvest population. (Received December 29, 2019).

- “Barely detectable levels” of pesticides or herbicides should trigger further investigation prior to the assessment of penalties, due to environmental contamination issues. (Received December 29, 2019).

Other concerns included:

- From processors/producers, concern that requiring tests for pesticides and heavy metals would negatively impact businesses, from both the producer/processor perspective:

  “*I own a 502 producer/processor and I just heard that there is discussion about adding mandatory heavy metal and pesticide testing for every 5-pound lot of product.*

  Well, if you want to finish the job of driving the small growers out of business, by all means proceed with the least cost-effective way of dealing with this "problem." The same effects can be obtained from a random testing program or from allowing harvest-sized batches, but hell, all those small growers are raking in the money, so they are ripe for a little more squeezing, right?

  And by the way, do you know how many people have been killed by "contaminated" weed worldwide in the history of man? Zero. Do you know how many have been sickened? Zero confirmed. Good thing you are addressing this problem! I feel safer already!”

- From labs, general concern that increasing lot size would negatively impact business:

  “*Standardized testing is preferred. Most labs are barely making it. Doubling lot size, millions in equipment. Some labs are undercutting budget. Currently, charge $90 for i502 testing (mycobio/potentcy/everything) and makes $6 profit. Others charge $70. Trace charges $180 for the same tests. Time of service payments would help. Proposed rules would cut revenue in half*.”

- Three processor/producers asserted that the public is disinterested in products tested for pesticides and heavy metals:

  “At this time consumers have the option to buy product that has been tested for heavy metals and pesticides in the form of DOH compliant products. Legislation establishing DOH certified product type were adopted in 2015 however consumer demand for these product types has remained tepid. The public has clearly demonstrated a lack of interest in products tested for pesticides and heavy metals and the consumers that are interested in these standards are already served by the DOH certification. In response to the public’s lack of interest in DOH compliant products some producer and processor licensees have sought regulatory interference in the marketplace in the form of increased testing costs and standards to stymie market competition. Such calls to “level the playing field” amount to predation through regulation.”

- Comments from consumers expressed concern that recreational products were not tested for pesticides and heavy metals:

"It has come to my attention that cannabis is (still) not tested for pesticides in the adult use market. This seems like it is a necessary test that may have been overlooked by the Liquor and Cannabis Board. **I am writing you today to ask that you review your rule making on this issue and analyze whether requiring pesticide testing in the adult use market makes sense for consumer and patient health and safety**. I realize that the data and research are still out onto whether pesticides are "bad" for you, but I would anticipate that a conservative approach, considering your mission, would make sense. I also recall seeing a story in The Stranger a while ago, that showcased a random selection of retail cannabis of which a large portion failed a pesticide screening. Even with that article in 2016, it appears that the Liquor and Cannabis Board has hesitated to address illegal pesticide usage in the 502 market. I kindly ask that you review your rules and regulations around mandatory pesticide testing for adult use products, while taking into account the effect your rule changes will have on licensees. ***Consumer safety should be the forefront of a state agencies concern, followed by making sure your rules do not overly burden the small businesses who are the backbone of the cannabis industry***." – LCB Rules in-box, 9/13/18

Comments Received During the First Public Hearing held July 8, 2020

See Attachment C.

Alternative Versions of the Rule and Least Burdensome Alternative

Two versions of draft conceptual rules were offered for stakeholder comment before the initial CR 102 was filed. Only one stakeholder offered alternative language, or specific suggested revisions. To date, and even after the original CR 102 was filed and at public hearing, no alternative language was offered. 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. Several attendees indicated that they would offer specific rule language, but at the time of original writing and as of this update on September 30, 2020, no specific language has been offered for consideration.

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 increases lot size to 10lb at Phase 2 of implementation.
Addition of pesticide and 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 pesticides and heavy metals with an incremental 12-month phase period to allow licensees businesses to adjust.

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.

Attachment A

Phase-in of Required Quality Control Testing	Lots of marijuana flowers or other material that will not be extracted	Marijuana Mix	Concentrate or extract made with hydrocarbons (solvent based made using n-butane, isobutane, propane, heptane, or other solvents or gases approved by the board of at least 99% purity)	Concentrate or extract made with a CO2 extractor like hash oil	Concentrate or extract made with ethanol	Concentrate or extract made with approved food grade solvent	Concentrate or extract (nonsolvent) such as kief, hash, rosin, or bubble hash	Infused cooking oil or fat in solid form
February 6, 2021 (Effective Date)								
Moisture analysis	√	√						
Potency analysis	√	√	√	√	√	√	√	√
Foreign matter inspection	√	√						
Microbiological screening	√	√				√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing
Mycotoxin screening	√	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing
Residual solvent test			√	√	√	√		
August 1, 2021(Ten pound lot size becomes effective)								
Moisture analysis	√	√						
Potency analysis	√	√	√	√	√	√	√	√
Foreign matter inspection	√	√						
Microbiological screening	√	√				√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing
Mycotoxin screening	√	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing
Residual solvent test			√	√	√	√		
Pesticides	√	√	√	√	√	√	√	√
February 1, 2022								
Moisture Content	√	√						
Potency analysis	√	√	√	√	√	√	√	√
Foreign matter inspection	√	√						
Microbiological screening	√	√				√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing
Mycotoxin screening	√	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing
Residual solvent test			√	√	√	√		
Pesticides	√	√	√	√	√	√	√	√
Heavy metals	√	√	√	√	√	√	√	√

Attachment B

Scenario	Number of Samples Tested Annually	$165 Per Sample[3]	$225 Per Sample[1]	$400 Per Sample[1]
Low # of Samples	72[1]	$11,880	$16,200	$28,800
High # of Samples	2,080[1]	$343,200	$468,000	$832,000
Average # of Samples	184[2]	$30,360	$41,400	$73,600
Median # of Samples	101[2]	$16,665	$22,725	$40,400

Notes:
[1] Estimates based off of information collected in interviews by Industrial Economics Incorporated, Spring 2019
[2] Figures based on traceability data, as of 1/2020
[3] Cost based on currently available pricing in Washington state, as of 1/2020

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