



Attachment A to CR-103

Concise Explanatory Statement: WAC Chapter 246-70, Marijuana Product Compliance

TOPIC	CITATION	COMMENTS ON PROPOSED RULES	AGENCY RESPONSE
General	Chapter 246-70 WAC	Concern that a supplemental CR-102 will negate the department's responsibility or willingness to address previous comments submitting during the public comment period and public hearing for the original CR-102.	<p>As required by the Administrative Procedure Act, the Department of Health (department) collected, saved and addresses in this document comments received during the entire public comment and hearing process. This began in February 2016 with the filing of the original rule proposal (CR-102) up through July 2016 for the supplemental rule proposal (CR-102).</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
High THC Products	WAC 246-70-040(2)	Tablets should be among the list of allowed High THC products. Like capsules, tablets are the most common in the pharmacy world. There's no reason this should not be an option.	<p>The department added tablets as an acceptable product type for High THC doses to provide patients another appropriate option. However, to clearly delineate these products from candy and help ensure children are not drawn to these products, the department is prohibiting the addition of any type of flavoring or sweetener.</p> <p><i>Was the rule changed as a result of these comments? Yes</i></p>
		"High THC" and "General Use" compliant cannabis or cannabis products are confusing. Concentrates (BHO, RSO, CO2) can be high in THC, but are not on the specific list of products classified as high THC compliant.	<p>High THC compliant products by definition are infused products sold by serving. Concentrates do not meet this definition and are not limited in their potency.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
High CBD Products	WAC 246-70-040(3)	A 25:1 CBD:THC ratio may be an obstacle to having high CBD medicines on the shelves, which many of my patients rely on.	<p>CBD products not meeting this ratio can be classified as "General Use" compliant under WAC 246-70-040(1). The department has further clarified this in the rule.</p> <p><i>Was the rule changed as a result of these comments? Yes</i></p>

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Testing: Cost	WAC 246-70-050	Small producers grow smaller, more frequent crops which translate to a higher rate of testing costs than the large outdoor producers. Costs can reach \$100,000 per year which can put small growers out of business.	<p>The department is committed to finding the right balance of ensuring patient safety and limiting testing costs. At this time we believe the amount of testing required cannot be adjusted down any further without compromising patient safety.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
Testing: Cost, Frequency	WAC 246-70-050	Washington will require more (and redundant) testing compared to Oregon or Colorado, making our products more expensive. Product that is turned into concentrates or extracts does not need to be tested twice. Washington would be the only state in the U.S. with this redundancy. This makes our business efforts uncompetitive with Oregon, increasing costs and diving down sales and tax revenue.	<p>Because the Washington State Liquor and Cannabis Board (WSLCB) is able to trace products from seed to sale including the capability to ensure testing is done at harvest or when a product is turned into a concentrate the department is changing the standard to only require testing at either harvest or when a concentrate is being created. This ensures patient safety while reducing the cost to the producer/processor.</p> <p><i>Was the rule changed as a result of these comments? Yes</i></p>
Testing: Cost, Frequency	WAC 246-70-050	Testing of plant products is not necessary if they are used for concentrates. A batch of concentrates is a better place to test. The extracts from concentrates are homogenized so as to represent the entire batch in one sample. Prior testing to this final product creates additional costs and is a waste of medical patient's money.	<p>Because the WSLCB is able to trace products from seed to sale including the capability to ensure testing is done at harvest or when a product is turned into a concentrate the department is changing our language to only require testing at either harvest or when a concentrate is being created. This ensures patient safety while reducing the cost to the producer/processor.</p> <p><i>Was the rule changed as a result of these comments? Yes</i></p>
Testing: Cost, Frequency	WAC 246-70-050	Testing costs in the department's economic impact statement of \$200 and higher is inaccurate. Tests average approximately \$800. The department's statement that additional testing will have a "minimal cost impact" is incorrect. Testing would occur during a bad time in the harvest-to-sale process. Adding in the other complexities and overhead costs to additional testing result in higher costs for the end user. This has a disproportionate effect on small businesses that produce smaller lots.	<p>The department has provided the best cost estimates cost available considering that these tests have not been done before in Washington. They are consistent with Nevada's costs. The department is committed to finding the right balance of ensuring patient safety and limiting testing costs. At this time we believe the amount of testing required cannot be adjusted down any further without compromising patient safety.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>

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Testing: Cost, Frequency	WAC 246-70-050	Testing a product more than once creates excessive and redundant costs for everyone in the industry. Once tested at harvest, the plant composition is documented and will not change. No other state requires this nor is it required by the pharmaceutical industry. This will drive consumers to Oregon or to the black market, which is the opposite of the State's goal.	Because the WSLCB is able to trace products from seed to sale including the capability to ensure testing is done at harvest or when a product is turned into a concentrate the department is changing the standard to only require testing at either harvest or when a concentrate is being created. This ensures patient safety while reducing the cost to the producer/processor. <i>Was the rule changed as a result of these comments? Yes</i>
Testing: Cost, Frequency	WAC 246-70-050	Post-processing batch testing is redundant if testing is required at the point of harvest. If post-harvest pesticide addition is a concern, prohibit the practice in rule. If microbial/heavy metal contamination is a concern, require testing after the processing stage prior to sale only. Redundant testing prior to processing doubles the testing cost and only makes money for state testing facilities.	Because the WSLCB is able to trace products from seed to sale including the capability to ensure testing is done at harvest or when a product is turned into a concentrate the department is changing the standard to only require testing at either harvest or when a concentrate is being created. This ensures patient safety while reducing the cost to the producer/processor. <i>Was the rule changed as a result of these comments? Yes</i>
Testing: Cost, Frequency	WAC 246-70-050	This proposal requires testing in addition to that which is required by the Liquor and Cannabis Board (LCB) in WAC 314-55-102. This is unnecessary and redundant. The testing in the Department of Health's proposal is fully comprehensive, useful, and much more stringent than testing as required by the LCB. This testing should be in lieu of, not in addition to, LCB testing. This redundancy shows ignorance of compliance law in general as it translates into practical business operations.	Testing in these rules is not redundant with the WSLCB rules. Testing for pesticides, heavy metals and mycotoxins is in addition to the other tests required by the WSLCB. The department was given authority to create higher standards for products that may be beneficial for patients. Patients have indicated they have conditions that make them particularly sensitive to pesticides and heavy metals. <i>Was the rule changed as a result of these comments? No</i>
Testing: State standards compared to other standards	WAC 246-70-050	This proposal creates unnecessary testing, tracking, expense, and paperwork. It is nowhere near to other closely related industry standards.	The department is committed to finding the right balance of ensuring patient safety and limiting quality assurance costs. At this time we believe the proposed standards cannot be adjusted down any further without compromising patient safety. <i>Was the rule changed as a result of these comments? No</i>

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Testing: State standards compared to other standards	WAC 246-70-050	Testing requirements should follow the recommendations and the experts at the United State Pharmacopeia, which is listed in the USP Standards section for drugs and nutritional supplements. This area of expertise is beyond the Washington State Department of Health (department) and should be aligned at the federal level with the Food and Drug Administration. The department has not shared documentation or thought process behind their proposal.	Testing requirements follow the American Herbal Pharmacopeia – Cannabis Inflorescence. This is considered to be the leading document for marijuana production. <i>Was the rule changed as a result of these comments?</i> No
Testing: Enforcement	WAC 246-70-050	Allowing marijuana product samples for testing to be self-selected by growers places too much trust in them. Growers and their staff have a high incentive to not lose money from crop failures, creating a high incentive to cheat the system. The state should employ an independent tester, paid for by a fee to the grower, to randomly collect samples from randomly selected growers. Such a failed test would mean the loss of their license.	The sampling procedures in these rules mirror the sampling procedures required for all marijuana products in the WSLCB rules. Creating a different standard would have been unduly confusing for producers, processors, and labs. <i>Was the rule changed as a result of these comments?</i> No
Testing: Imported Cannabinoids	WAC 246-70-050(1)	Where are the imported cannabinoids coming from and how will they be tested? There are many natural products/extracts added to cannabis in retail shops (melatonin included), and it is irresponsible to allow this without proper oversight.	The department created a requirement to test imported cannabinoids because they are coming from outside the regulated Washington market. Testing for heavy metals and pesticides performed by an WSLCB certified third party lab prior to the addition of imported cannabinoids being added to a marijuana product is required to ensure their lack of contaminants. <i>Was the rule changed as a result of these comments?</i> No
Testing: Marijuana Product Batches and Lots	WAC 246-70-030(2) 246-70-050(1)	There is no need to combine lots from different strains or from same strains grown differently into a single batch. Normal farm husbandry does not do this. A batch should be more narrowly defined to only allow for plants from the same harvest and strain, and farmed in the same manner.	To more narrowly define a batch in this way would be a detriment for the majority of growers who may combine strains into a single concentrate or extract. The current definition allows for the best flexibility for producers and processors. <i>Was the rule changed as a result of these comments?</i> No

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Testing: Marijuana Product Batches and Lots	WAC 246-70-030(10) 246-70-050	Lot sizes need to be clearly defined for testing. For extractions, processors are exploiting a loop hole that allows for the creation of very large lot sizes. The lot size should be limited to the size of the column per run.	To more narrowly define lot sizes puts a larger burden on the producer/processor without providing additional safety because batches of concentrates and extracts are homogenized regardless of size. <i>Was the rule changed as a result of these comments? No</i>
Testing: Standards, Re- testing	WAC 246-70-050(2)	Pesticide testing should have established actions levels and detection limits. This enforces the use of platforms that can detect very low levels of residues and sets a baseline limiting false negatives and false positive to less than one percent.	The department has adopted by reference the action levels set by the WSLCB. <i>Was the rule changed as a result of these comments? Yes</i>
Testing: Standards, Levels, Re-testing	WAC 246-70-050(1)	Products failing an initial test should be allowed an opportunity for a "clean up" and re-test.	Under current WSLCB rules a lot that fails testing must be recalled. The presence of pesticides, heavy metals, or mycotoxins is injurious to public health. At this time there is insufficient evidence regarding remediation to allow a contaminated product to enter the market. <i>Was the rule changed as a result of these comments? No</i>
Testing: Standards, Levels, Re-testing	WAC 246-70-050	Having a rotating list of pesticides to test is not optimal. It takes an inordinate amount of time and money. The reliability of the data can come into question.	The department has worked carefully with the Department of Agriculture, the WSLCB, and stakeholders in this area. A rotating list of pesticides will ensure producers do not become complacent by simply using products not on the testing list. <i>Was the rule changed as a result of these comments? No</i>
Testing: Heavy Metals, Levels	WAC 246-70-050(3)	Heavy metals testing should have limits of detection to accommodate XRF and EDX technology.	The heavy metal standards were set according to the standards set in the American Herbal Pharmacopeia – Cannabis Inflorescence which is relied upon by several states. <i>Was the rule changed as a result of these comments? No</i>