



CR102 Memorandum

Regarding WAC 314-55-010 – Definitions; New Section WAC 314-55-550 – Marijuana vapor products; New Section WAC 314-55-1055 – Ingredient Disclosure

Date: December 9, 2020
Presented by: Casey Schaufler, Policy and Rules Coordinator

Background

On September 27, 2019, Governor Inslee issued Executive Order 19-03 to address an outbreak of lung injuries emerging in previously healthy individuals who had vaped THC or nicotine vapor products.

Under direction of Executive Order 19-03, on October 10, 2019, the Washington State Board of Health (SBOH) issued emergency rules prohibiting the sale of flavored vapor products by persons licensed under chapter 69.50 RCW or chapter 70.345 RCW.

On October 16, 2019, the Washington State Liquor and Cannabis Board (Board) adopted an emergency rule as WSR 19-21-100 creating new WAC 314-55-1055 requiring manufacturers of THC vapor products to disclose all compounds, including ingredients, solvents, additives, etc. used in the production and processing as well as the source of all vapor products as directed by Executive Order 19-03.

On November 20, 2019, the SBOH adopted an emergency rule as WSR 19-24-001 on November 20, 2019, prohibiting the sale of vapor products containing vitamin E acetate. The SBOH found that the outbreak of lung disease continued to grow, and that the adoption of an emergency rule prohibiting the sale of vapor products containing vitamin E acetate was necessary for the preservation of the public health, safety, and general welfare. The SBOH relied on the following to support its finding:

- In July 2019, the United States Centers for Disease Control and Prevention (CDC), United States Food and Drug Administration (FDA), state and local health departments, and other clinical and public health partners began investigating outbreaks of lung injury associated with e-cigarette product use, or vaping.
- In September 2019, the CDC activated its Emergency Operations Center to aid in the investigation of the multistate outbreak.

- As of November 13, 2019, there have been two thousand one hundred seventy-two confirmed cases reported across forty-nine states, the District of Columbia, Puerto Rico and the United States Virgin Islands, including forty-two deaths confirmed in twenty-four states. Fourteen cases of lung injury have been reported in Washington State.
- As part of the investigation into the multistate outbreak of lung disease associated with the use of vapor products, the CDC conducted laboratory tests of twenty-nine samples of fluid collected from the lungs of patients with vaping-associated lung disease from ten states. An article released on November 8, 2019, showed that all of the samples contained vitamin E acetate, providing direct evidence of vitamin E acetate at the primary site of injury in the lungs. Vitamin E acetate is a chemical that is used as an additive or thickening ingredient in vapor products. The CDC has not determined that vitamin E acetate is present in only THC vapor products or only non-THC vapor products. THC was identified in eighty-two percent of the samples, and nicotine was identified in sixty-two percent of the samples. None of a range of other potential chemicals of concern was detected in the samples, but evidence is not yet sufficient to rule out the contribution of other chemicals, substances, or product sources to the disease. The CDC has identified vitamin E acetate as a chemical of concern and stated that, until the relationship of vitamin E acetate and lung health is better characterized, it is important that vitamin E acetate not be added to vapor products.

On February 5, 2020, the Board extended its emergency rule originally filed as WSR 19-21-100 that created new WAC 314-55-1055 requiring manufacturers of THC vapor products to disclose all compounds, including ingredients, solvents, additives, etc. used in the production and processing as well as the source of all vapor products as directed by Executive Order 19-03 as WSR 20-05-004.

The SBOH emergency flavor ban expired on or about February 7, 2020.

On March 19, 2020, the SBOH extended its emergency rule concerning the prohibition of the sale of vapor products containing vitamin E acetate as WSR 20-08-007.

On March 25, 2020, House Bill (HB) 2826 (Chapter 133, Laws of 2020), now codified in RCW 69.50.101, RCW 69.50.327, RCW 69.50.342, was enacted in response to concerns related to marijuana vapor product and vapor related lung illnesses. The legislation contained an emergency clause, and in its intent

section, found that “recent reports of lung illnesses associated with vapor products” demanded “serious attention by the state in the interest of protecting public health and preventing youth access. While state law grants the liquor and cannabis board broad authority to regulate vapor products containing marijuana, the legislature finds that risks to public health and youth access can be mitigated by clarifying that the board is granted specific authority to prohibit the use of any additive, solvent, ingredient, or compound in marijuana vapor product production and processing and to prohibit any device used in conjunction with a marijuana vapor product.”

On May 27, 2020, the Board issued its own emergency rule as WSR 20-12-035 as new WAC 314-55-1065 prohibiting the sale of vapor products containing vitamin E acetate consistent with the authority granted by HB 2826, now codified in RCW 69.50.101, RCW 69.50.327, RCW 69.50.342.

Also on May 27, 2020, the Board rescinded WSR 20-05-004, and replaced it with WSR 20-12-039, extending the requirements for disclosure of all ingredients used in the production of marijuana concentrates for inhalation and marijuana extracts for inhalation consistent as described in WAC 314-55-105, consistent with the authority granted by HB 2826, now codified in RCW 69.50.101, RCW 69.50.327, RCW 69.50.342.

On July 17, 2020, the SBOH extended its emergency rule concerning the prohibition of the sale of vapor products containing vitamin E acetate as WSR 20-15-117.

On September 16, 2020, the Board extended emergency rule WAC 314-55-1055 as WSR 20-19-083, and emergency rule WAC 314-55-1065 as WSR 20-19-080. Each of these rules will expire on January 14, 2021.

On November 15, 2020, the SBOH adopted WAC 246-80-012 as WSR 20-23-006, permanently prohibiting the sale of vapor products containing vitamin E acetate. The prohibition applies to any person licensed under chapter 69.50 or 70.345 RCW. The rule went into effect immediately upon filing.

WSLCB Stakeholder Engagement

Comments received after the CR 101 was filed for this project on July 8, 2020 are presented in Attachment A.

The Board hosted two Listen & Learn sessions to provide an opportunity for licensees and other interested parties to review conceptual draft rules for the implementation of HB 2826.

The first session was held virtually on September 1, 2020, with approximately 100 people in virtual attendance via WebEx. The purpose of this session was to

review the conceptual draft rules necessary for the implementation of new definitions as required by HB 2826. Conceptual definitions for “characterizing flavor” and “terpenes, botanical terpenes, synthetic terpenes, terpenoids” were shared as new WAC sections 314-55-010(4) and 314-55-010(40), respectively. Participants were asked to indicate what they liked, didn’t like, and to offer alternative language for the conceptual draft rules. These definitions had been made available to licensees and other interested parties two weeks prior when the first Listen & Learn Session invitation was sent via GovDelivery on August 18, 2020. Comments received are presented in Attachment B.

The second session was held virtually on September 29, 2020, with approximately 70 people in virtual attendance via WebEx. The purpose of this session was to review the conceptual draft rules for a new section of WAC, WAC 314-55-550 – Marijuana Vapor Products, establishing procedures of the Board to regulate marijuana vapor products consistent with HB 2826. Additionally, this session also reviewed the content and format of the marijuana vapor product disclosure form. Board staff indicated to participants that the form itself was not necessarily part of the rulemaking effort, but that Board staff were using this as an opportunity for identifying pain points and for areas of improvement in the disclosure process. Participants were asked to indicate what they liked, didn’t like, and to offer alternative language for the conceptual draft rules and the disclosure form. The conceptual draft rules for WAC 314-55-550 and the disclosure form had been made available to licensees and other interested parties two weeks prior when the second Listen & Learn Session invitation was sent via GovDelivery on September 16, 2020. Comments received are presented in Attachment B.

Rule Necessity

New and amendment of existing rules is necessary to allow the WSLCB to implement marijuana vapor product regulation consistent with HB 2826, now codified in RCW 69.50.101, RCW 69.50.327, RCW 69.50.342 and to establish definitions as appropriate and necessary.

Description of Rule Changes

Amended Subsection. WAC 314-55-010(4) – Adds a definition for “characterizing flavor.”

Amended Subsection. WAC 314-55-010(40) – Adds a definition for “terpenes” as well as sub-definitions for “botanical terpenes,” “synthetic terpenes,” and “terpenoids.”

New Section. WAC 314-55-550 – Establishes procedures to prohibit devices, additives, solvents, ingredients, or compounds in the production or use of

marijuana vapor products. Establishes process to determine if devices, additives, solvents, ingredients, or compounds in the production or use of marijuana vapor products should no longer be prohibited.

New Section. WAC 314-55-1055 – Affirms existing emergency protocols that require marijuana licensees to disclose all compounds, including but not limited to ingredients, solvents, additives, preservatives, thickening agents, terpenes, and other substances used to produce or added to marijuana concentrates for inhalation or marijuana-infused extracts for inhalation at any point during production and processing, regardless of source or origin. Disclosure must be made to the board on forms provided by the board.

Attachments:

Attachment A (Summary of comments received following the filing of the CR 101 on July 8, 2020, as WSR 20-15-041)

Attachment B (Public comment, as recorded by Board staff, received during Listen & Learn Session #1 held September 1, 2020)

Attachment C (Public comment, as recorded by Board staff, received during Listen & Learn Session #2 held September 29, 2020)

Public Comment — Marijuana Vapor Products
Attachment A – Written comment received following CR101 filing on July 8, 2020

| Source | Commenter | Date Received | Comment |
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| <i>Email</i> | David Heldreth | 7/9/2020 | <p>NEW SECTION. Sec. 4. A new section is added to chapter 69.50 RCW to read as follows:18 19 (1) Except as provided in subsection (2) of this section, 20 marijuana processors may incorporate in marijuana vapor products a 21 characterizing flavor if the characterizing flavor is derived from 22 botanical terpenes naturally occurring in the cannabis plant, 23 regardless of source, and if the characterizing flavor mimics the 24 terpene profile found in a cannabis plant. Characterizing flavors 25 authorized under this section do not include any synthetic terpenes. 26 (2) If the board determines a characterizing flavor otherwise 27 authorized under this section may pose a risk to public health or 28 youth access, the board may, by rule adopted under RCW 69.50.342, 29 prohibit the use in marijuana vapor products of such a characterizing flavor.</p> <p>The state law clearly states that aside from cannabis-derived ingredients the only flavor that may be used is botanical terpenes. Botanical terpenes are a self defining category or classification with strict definitions. Botanical means coming from a plant for the source of the materials and terpenes are a class of chemical compounds. The key here is that the law does NOT say terpenes and similar classes of compounds, it does NOT say other compounds found in cannabis. It specifically says only terpenes and only terpenes that are sourced from plants. Thus terpenes from fungi, bacteria or any other source must be banned.</p> <p>As such only terpenes which are compounds in that exact class by scientific definition may be used. Terpenes are specifically hydrocarbons which only contain carbon and hydrogen atoms and NO oxygen or other atoms. They also must contain isoprene units in their structure.</p> <p>Terpenoids are a similar class of compounds which are similar to terpenes, as terpenes and terpenoids are both isoprenoids, but terpenoids are NOT terpenes. They contain oxygen and other compounds which explicitly deny their ability to be categorized as terpenes.</p> <p>As the law requires only terpenes to be allowed (unless sourced from cannabis), terpenoids and related compounds may NOT be legally utilized in cannabis products under the law. Also while the law gives the WSLCB the ability to make stricter rules banning more compounds there is no such allowance for allowing something the law does not allow. As such the WSLCB has no authority to allow terpenoids in cannabis products as the law does not allow them and thus any definition the WSLCB derives for botanical terpene must exclude terpenoids.</p> <p>Menthol, terpineol, camphor, citral are all examples of terpenoids or compounds with oxygen and other atoms which thus disqualify them from use or definition as a terpene. The WSLCB should as such define botanical terpenes as the chemical class is defined in all science otherwise the WSLCB will be violating the law. Here is the correct definition: "hydrocarbons, compounds containing only hydrogen and carbon, which also contain an isoprene structure and are sourced from plants.</p> <p>I also believe the entire formula of all flavor additives need to be disclosed to the WSLCB and put on packaging and labels. Currently companies are placing the name of a flavoring companies profile or flavor, but not the entire break down of the percentages and names of each compound. This is also required under the new vapor law. Companies attempt to say this will violate their proprietary formulas, but there is no protection for that in the vapor law or allowance to use that as a reason to not disclose. This is because our government has ruled that human health and truth in labeling is more important than IP. Especially when these brands are responsible for using tainted ingredients that led to the vape illness epidemic. As a former employee of a company that made flavor for vaping I can attest to the danger of allowing noncannabis ingredients to enter the market. I myself refuse to vape anything that isn't full cannabis or utilize any similar products because of what I know.</p> <p>New Section (n) Requirements for processors to submit under oath to the department of health a complete list of all constituent substances and the amount and sources thereof in each marijuana vapor product, including all additives, thickening agents, preservatives, compounds, and any other substance used in the production and processing of each marijuana vapor product.</p> |

Public Comment — Marijuana Vapor Products

Attachment A – Written comment received following CR101 filing on July 8, 2020

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| <p><i>Email</i></p> | <p>David Heldreth</p> | <p>7/24/2020</p> | <p>I'm forwarding a document I've shared with the OLCC which demonstrates that the terpene stereoisomers/enantiomers which are found in botanicals are not representational of those found in cannabis. As such under the law which was passed they may not be allowed in inhalation cannabis products as they are not mimicking the terpene profiles Found in cannabis and are even using some terpene enantiomers which are not found in cannabis. As such they should not be allowed.</p> <p>Begin forwarded message:</p> <p>Anthony Geltosky, Thanks for taking the time to speak today. Apologies for the lateness with this document, but I returned home late. I've attached it as a .docx and .pdf for your use. It outlines the variations in cannabis and other botanicals, difficulties in testing and methods to use as well as how these variations affect the body</p> |
| <p><i>Email</i></p> | <p>Michelle Anderson</p> | <p>8/21/2020</p> | <p>I do not feel that FLAVOR of any kind needs to be removed as flavorings is NOT what caused the lung damage to people. The Vitamin E Acetate is what caused the damage.</p> <p>I feel that "any place youth may congregate unrestricted or unsupervised" should cover everything in the way of restrictions and leaves room for improvement.</p> <p>I feel "School Grounds" should be separated and considered 24/7 enforceable from ANY drugs/alcohol of any kind. I wish that Park and school zones were 24/7 too!</p> <p>You guys are doing a great job! The listen and learn forums that take in everyone's opinion and then makes the best rules are DEFINITELY the way to continue governing! EXCELLENT Job!!</p> |
| <p><i>Email</i></p> | <p>David Heldreth</p> | <p>8/27/2020</p> | <p>As the Washington State law as written says that only botanical terpenes may be used this indicates that simply defining botanical terpenes as constituents derived from... is insufficient, the law clearly indicates that only terpenes, not other constituents from botanical sources may be used. As such any other compounds used would be a violation of Washington State law. The law allows for the WSLCB to make more compounds restricted, but not to allow any additional compounds. As such all wording which extends to the use of anything other than the exact chemical class of terpenes is now allowed and must be altered as I have done below. Terpenoids are not actually chemically terpenes. They are related, but separate groups, simply amending them to have the same meaning under Washington regulation would be at the same time a violation of Washington State law as the law does not allow additional compounds, but only terpenes, again not related compounds.</p> <p>40. "Terpenoids" means the natural products and related compounds formally derived from isoprene units, or "isoprenoids," that have the same meaning as that found in the current version of the International Union of Pure and Applied Chemistry (IUPAC) and as hereafter amended.</p> <p>"Terpenes" means a class of compounds that imparts smell, taste, or both occurring in the cannabis plant which consist of a carbon skeleton derived from isoprene units <u>and only hydrogen or carbon atoms</u>. The word "terpene" may includes, but is not limited to the following:</p> <p>(a) "Botanical terpenes" means constituents terpenes derived from a spice, fruit, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, or leaf or similar plant material. Their significant function in cannabis products is flavoring rather than to act as a drug.</p> <p>This includes:</p> <p>(i) <u>Terpenes derived from</u> essential oil, which is natural oil typically obtained by distillation and possessing the characteristic fragrance of the plant or other source from which it is extracted;</p> <p>(ii) <u>Terpenes derived</u> from oleoresin, which is a natural or artificial mixture of essential oils and a resin;</p> <p>(iii) <u>Terpenes derived from</u> Distillate; or</p> <p>(iv) Any product of roasting, heating, or enzymolysis which contains <u>only</u> terpenes.</p> |

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| | | | <p>(b) "Synthetic terpenes" means any terpene that does not occur in the cannabis plant, or in other botanical sources, and is produced through chemical manipulation in a laboratory or similar facility.</p> <p>(c) "Terpenoids" means the natural products and related compounds formally derived from isoprene units, or "isoprenoids," that have the same meaning as that found in the current version of the International Union of Pure and Applied Chemistry (IUPAC) and as hereafter amended.</p> |
| <i>Email</i> | Crystal Oliver | 9/1/2020 | <p>Comment 1: I tend to agree with Chris Masse's comment about the definition of characterizing flavor needing additional work when the language of the bill is considered which reads "marijuana processors may incorporate in marijuana vapor products a characterizing flavor if the characterizing flavor is derived from botanical terpenes naturally occurring in the cannabis plant, regardless of source, and if the characterizing flavor mimics the terpene profile found in a cannabis plant. Characterizing flavors authorized under this section do not include any synthetic terpenes." The legislative language indicates that there exists characterizing flavor that mimic the terpene profile of cannabis and other types of characterizing flavors thus it does seem confusing to define it in WAC as a "a noticeable taste, other than one of cannabis" While my verbal comments focused on the second section of the definition of characterizing flavor including the word "noticeable" a second time and unnecessarily complicating the definition I wish to retract that recommendation and offer this definition instead: Characterizing flavor means a clearly noticeable taste.</p> <p>Comment 2: For the definition of botanical terpenes, the order should be revised from most used to least commonly used and vegetable juice seems unnecessary since vegetable is listed. The phrase "rather than to act as a drug" should be stricken as "drug" has a very specific definition and meaning in RCW 69.50 and seems inappropriate to add here. We also agree that edible yeast is not a botanical. Consider this definition instead: Botanical terpenes means aromatic constituents derived from an herb, fruit, or vegetable's bark, bud, root, leaf or similar plant material. Their significant function in cannabis products is flavoring. This includes:</p> <p>Comment 3: We question why "oleoresin" is listed as a botanical terpene. It can contain terpenes but is not a botanical terpene. While oleoresin is one of the products of extraction, we are not certain if it is something that should be permitted as an additive to products that are inhaled. It would seem that lumping it under the definition of "botanical terpenes" may complicate future rule making if the WSLCB determines that they do not want to allow its use as an additive. Consider pulling "oleoresin" out of the definition of botanical terpenes and making it a standalone definition.</p> <p>Comment 4: We question why "distillate" is listed as a botanical terpene as well. The term distillate in the marijuana industry commonly refers to distilled or purified cannabinoids which have generally had terpenes removed as part of the distillation process. We wonder if the WSLCB perhaps meant to include "hydrolat" defined as "distilled water enriched with plant oil." instead?</p> <p>Comment 5: We like the idea of defining additives in WAC as there has been a trend in the market away from whole plant extracts towards distillate's with additives such as high terpene extracts or other terpenes yet packaging does not clearly communicate this difference to consumers despite WAC 314-55-105 (2)(e)(vii) requiring disclosure of additives. Consider defining additive as "any and all substances that are added to a a concentrate after extraction"</p> |

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| <p><i>Email</i></p> | <p>Brooke Davies</p> | <p>9/1/2020</p> | <p>I wanted to let you know that I have a conflict with the Listen and Learn Session today. I will try my best to join late - however I may miss the meeting all together. I know today you are just discussing the definitions. I have held a few meetings with my members on this section and encouraged them all to participate today if they have strong feelings on this draft. In general WACA member feedback can on 010 Section (4) and (40) is summarized below:</p> <p>WAC 314-55-010 (4) - Definition of Characterizing Flavor</p> <p>This definition is in conflict with HB 2826 which expressly allows for characterizing flavor that mimics the flavor of cannabis.</p> <p>- at this time I do not have suggested language but will defer to our members who are participating in the listen and learn session today. Since we discussed these rules we have had more conversations about the purpose of this rule set and heard that it is not the LCB intention to regulate characterizing flavor but instead to set up a process to recall a substance if you need to, this could potentially change our approach to feedback.</p> <p>WAC 314-55-010 (40)(a) - Botanical terpene</p> <p>recommend striking the following from the definition: Their significant function in cannabis products is flavoring rather than to act as a drug.</p> |
| <p><i>Email</i></p> | <p>Johanna Williamson, Orchid Essentials</p> | <p>9/1/2020</p> | <p>Thank you for speaking with our Director of Compliance, Laurie Andrade the other day. She followed up with us on your conversation and as a result, we would like to provide you with the following:</p> <ol style="list-style-type: none"> 1. Our statement and review of proposed rules (designed for discussion only). 2. List of Ingredients - Lemon Burst - An example of a list of ingredients that comes with every product that goes out of our terpene manufacturer, Eybna's facility. 3. Cannabis EO vs. Terpenes : Chromatogram showing cannabis strain's essential oil vs the recreated terpene profile crafted by Eybna, highlighting a crucial step in Eybna's development process where precision and consistency is achieved in every batch 4. Terpenoids as therapeutic drugs and pharmaceutical agents - Discussing the several therapeutic properties of terpenes and their usage in the pharmaceutical world. 5. Limonene Safety Evaluation - Evaluating the safety of Limonene via inhalation 6. Pinene Safety Evaluation - Evaluating the safety of Alpha Pinene via inhalation 7. Eybna's contact information and list of experts |
| <p><i>Email</i></p> | <p>Johanna Williamson, Orchid Essentials (pt 1)</p> | <p>9/1/2020</p> | <p>Here is a copy of the statement by our CEO in regards to the decisions you are trying to make in Washington around botanical terpenes (also included as an attached doc.). Please review all and let us know if you have any feedback, if we can be of further assistance, or how we can participate further in providing information for your committees and board on this topic:</p> <p>To whom it may concern,</p> <p>This statement is in reference to the current discussions happening in Washington around banning additives in cannabis products - specifically terpenes derived from plants other than cannabis. We just went through this process in both Oregon and California, both of whom ultimately chose not to implement an outright ban on these products, because there was no evidence presented that could prove them to be harmful.</p> <p>In fact, our research and evidence (to be submitted to you for consideration) actually indicate that botanical terpenes manufactured in safe, clean, ISO-certified facilities with quality standards at the highest levels - are actually LESS toxic than the current cannabis-derived terpenes currently being used and manufactured without any regulation around quality control or best practices for manufacturing.</p> <p>The alternative that we supported for our agency in Oregon was: Instead of banning terpenes - that they issue requirements of terpene manufacturers, including good manufacturing practices that are held to a specific standard, as well as being required to openly provide a list</p> |

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| | | | <p>of ingredients used in their manufacturing processes.</p> <p>We urge you to review the science supporting the use and clarifying the effects of terpenes derived from non-cannabis plants, and instead of assuming the danger in this particular product (an assumption of which there is no science to support), that you focus more on fighting substances that have been proven to be harmful (such as concentrated levels of hydrogen cyanide in black market products or the investigation of squalene and MCT being used in vape). We would also like to point out that the quality of manufacturing and emissions testing of hardware should be considered on an equally relevant playing field when asking the question, “How can we prevent more lung illnesses and deaths?”.</p> <p>Our company was partially founded on the development of the highest quality vape hardware on the market, in addition to AFNOR/EU levels of emissions testing (testing the actual vape coming out of the hardware, not just the heavy metals or leeching potential) required in all of the products we make and use.</p> <p>Please review the documents we’ve submitted from our partners at the University of Jerusalem in Isreal on the manufacturing and effects of botanical terpenes, and please also reach out to us with any questions on hardware safety and how that plays a part in this conversation. Should you wish to speak with the scientists who compiled these documents for further insight, we will connect you right away.</p> <p>In addition, please review these comments on the recent Draft Rules for Discussion and Preproposal Statement of Inquiry on this topic:</p> |
| <p><i>Email</i></p> | <p>Johanna Williamson, Orchid Essentials (pt 2)</p> | <p>9/1/2020</p> | <p>From Preproposal Statement of Inquiry CR-101:</p> <p>“However, before adopting either of these types of rules, the Board must have determined, following a consultation with the Department of Health (DOH), or any other authority the Board deems appropriate, the device, additive, solvent, ingredient, or compound may pose a risk to public health or youth access.”</p> <p>By determining that a compound “MAY” pose a risk, rather than determining that a compound DOES propose a risk, backed by scientific evidence, the state runs the risk of creating a false sense of security and a diversion of focus around something that “MAY” actually NOT be the culprit! This decision needs to be based on fact, not opinion.</p> <p>From WAC 314-55-010 Conceptual Rules Designed for Discussion Only:</p> <p>““Botanical terpenes” means constituents derived from a spice, fruit, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, or leaf or similar plant material. Their significant function in cannabis products is flavoring rather than to act as a drug. This includes:”</p> <p>This is incorrect. The EFFECTS of terpenes are equally as important, if not more so as the smell and flavor that they impart. Please see our list of FDA approved pharmaceutical medications using botanical terpenes for effect, not flavor.</p> <p>“(b) “Synthetic terpenes” means any terpene that does not occur in the cannabis plant, or in other botanical sources, and is produced through chemical manipulation in a laboratory or similar facility.”</p> <p>This is also somewhat misleading, as botanical terpenes can be formulated using plant sources in a laboratory or similar facility.</p> <p>“(2) Procedure for prohibited substances. (a) The Board may prohibit any type of device used in conjunction with a marijuana vapor product, and may prohibit the use of any type of additive, solvent, ingredient, or compound in the production of marijuana vapor products that may pose a risk to public health or youth access.”</p> <p>We urge you to consider that the Board’s authority over a ban on anything be WHEN they have scientific evidence available to prove the</p> |

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| | | | <p>exact and particular compound that is causing risk to public health. Rather than giving authority to ban things (which could be the WRONG things, creating a false sense of security and further endangering the public), based on opinion, a feeling, a general agreement, rather than actual scientific data.</p> |
| <i>Email</i> | Stacey Okland | 9/2/2020 | <p>I was on the call when WAC 314-55-010 (4) was discussed and the only thing I would possibly add is something to help define noticeable taste. Tastes include bitter, sour, sweet, salty, and savory according to this link there is also astringent and false heat and false cold . What is Taste?--> https://www.scienceofcooking.com/about_taste.htm</p> <p>What is Taste? Taste, Smell and more come into play in producing the right flavor</p> <p>Adding this could help minimize confusion when it comes to what is a flavor.</p> <p>I do not have anything to add to WAC 314-55-010 (40) at this time.</p> |
| <i>Email</i> | Sarah Ross-Viles, Seattle & King County Public Health | 9/3/2020 | <p>I hope you are well. I wanted to follow up on my comment from the call earlier this week. I am CCing members of the YMPEP Practice Collaborative Retailer Education Workgroup, who are interested in these rules.</p> <p>Is it possible to import this definition into the WAC and add language that, "Youth access is to be considered on its own merits and not mitigated against older adult appeal and marketability." RCW 69.50.101(xx) "Youth access" means the level of interest persons under the age of twenty-one may have in a vapor product, as well as the degree to which the product is available or appealing to such persons, and the likelihood of initiation, use, or addiction by adolescents and young adults.</p> <p>Procedurably, I am not sure if the RCW definitions should also appear in the WAC. If not, then only the line above is necessary and would probably not be in the definitions.</p> |
| <i>Email</i> | Lukas Hunter (pt 1) | 9/15/2020 | |

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| | | | <p>Revision of Section 4: (4): “Characterizing flavor” means a clearly noticeable taste, other than one of cannabis, resulting from an additive or combination of additives, including but not limited to fruit, spice, herbs, alcohol, candy, or menthol, or that is noticeable before or during consumption of the cannabis product. This section although does take a different route than the language passed into statute (HB 2826) ultimately it accomplishes the same end goal of restricting flavors in MJ vapor products. For consistency the term “cannabis” should be replaced with “marijuana” as cannabis is not defined in statute or defined in rule, where the term marijuana is the basis for all regulated cannabis definitions. I believe the utilization of the term “Taste” is paramount in this definition as it provides clear guidelines to consumers and processors and doesn’t need to be elaborated on to create ambiguity within the rule. Finally further description prior to the first mention of marijuana. I would hope to see the following changes made: (4): “Characterizing flavor” means a clearly noticeable taste, other than one of what naturally occurs in cannabis marijuana, resulting from an additive or combination of additives, including but not limited to fruit, spice, herbs, alcohol, candy, or menthol, or that is noticeable before or during consumption of the cannabis marijuana product.</p> <p>(New Section): “Marijuana Vapor Product” With the implementation of rule focusing on marijuana vapor products I believe we should add a section defining marijuana vapor distinctly from marijuana concentrates. I believe the following language would be an appropriate substitute: “Marijuana Vapor Product” A marijuana concentrate that is consumed by the utilization of a heating element and does not require the combustion of the marijuana concentrate for consumption.</p> |
| <p><i>Email</i></p> | <p>Lukas Hunter (pt 2)</p> | <p>9/15/2020</p> | <p>Revision of Section 40: (40) “Terpenes” means a class of compounds that imparts smell, taste, or both occurring in the cannabis plant which consist of a carbon skeleton derived from isoprene units. The word “terpene” may include, but is not limited to the following: (a) “Botanical terpenes” means constituents derived from a spice, fruit, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, or leaf or similar plant material. Their significant function in cannabis products is flavoring rather than to act as a drug. This includes: (i) Essential oil, which is natural oil typically obtained by distillation and possessing the characteristic fragrance of the plant or other source from which it is extracted; (ii) Oleoresin, which is a natural or artificial mixture of essential oils and a resin; (iii) Distillate; or (iv) Any product of roasting, heating, or enzymolysis which contains terpene. (b) “Synthetic terpenes” means any terpene that does not occur in the cannabis plant, or in other botanical sources, and is produced through chemical manipulation in a laboratory or similar facility. (c) “Terpenoids” means the natural products and related compounds formally derived from isoprene units, or “isoprenoids,” that have the same meaning as that found in the current version of the International Union of Pure and Applied Chemistry (IUPAC) and as hereafter amended. This is a challenging section to grab a hold of as the research and understanding of cannabis terpenes and terpenoids is still evolving. I like a substantial part of the draft conceptual rules here but would like to see a few changes/amendments. 40, (a) Botanical Terpenes. This section could be simplified in its examples and the end section referring to the function is inappropriate. As we move forward with taking marijuana out of prohibition to refer to botanical flavoring as “act as a drug” seems regressive. Besides the regression, we are aware of the effects of the naturally occurring terpenes in cannabis having a drastic effect on the consumers endocannabinoid system. To state botanical terpenes may not have an effect on the consumers endocannabinoid system seems limiting. The request for the removal of this language is not to “open a door”, but to recognize that these naturally occurring terpenes can have an effect</p> |

Public Comment — Marijuana Vapor Products

Attachment A – Written comment received following CR101 filing on July 8, 2020

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| | | | <p>on a person’s experience with the cannabis product. Additionally in the closing statement “this includes:” I would like to see “this includes but is not limited to” this language provides the industry with the ability to continue to develop new means of extracting and infusing botanical terpenes, and there is not a limiting factor of how botanical terpenes are derived in HB 2826.</p> <p>With the above statements in mind I would like to propose the following language: “Botanical terpenes” means constituents derived from a spice, fruit, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, or leaf or similar plant material. Their significant function in cannabis products is flavoring rather than to act as a drug. This includes, but is not limited to: (i) Essential oil, which is natural oil typically obtained by distillation and possessing the characteristic fragrance of the plant or other source from which it is extracted; (ii) Oleoresin, which is a natural or artificial mixture of essential oils and a resin; (iii) Distillate; or (iviii) Any product of roasting, heating, or enzymolysis which contains terpene.</p> <p>40, (b) “Synthetic Terpenes”. This section does a good job with defining and providing clarity as to what a synthetic terpene is and further assisting the reader in understanding what cannot be in a marijuana vapor product. The only thing I would like to propose is to utilize a defined term in this section to further bolster the definition of a synthetic terpene. I believe this could be accomplished by removing the language “chemical manipulation” and replacing it with “combining non-terpenoid compounds”.</p> <p>(b) “Synthetic terpenes” means any terpene that does not occur in the cannabis sativa plant, or in other botanical sources, and is produced through combining non-terpenoid compounds chemical manipulation in a laboratory or similar facility.</p> |
| <i>Email</i> | NW Cannabis Solutions, Becca Burhardi, Kelsey Holstrom | 9/29/2020 | <p>Disclosure Form</p> <ul style="list-style-type: none"> - In question #3 under the Additives heading, Alpha bisabolol is listed as a thickener; it is also a common terpene – how is the LCB determining which terpenes are considered thickeners and why is alpha bisabolol listed here? - #4 & #5 under the Additives heading, #4 reads “Do you flavor your product with terpenes derived ‘directly and solely from marijuana as defined by RCW 69.50.101, hemp plants grown and tested by state law, or from another biological source” and #5 reads “Do you flavor your product with botanically-derived terpenes” I don’t understand the distinction between these questions; they appear redundant. - Under Additives currently prohibited heading, #1 asks if the vapor product is flavored with “synthetic terpenes or essential oils” – however, essential oils is listed under the LCB’s definition of “botanical terpenes”, so it does not appear accurate to disclose them in the prohibited heading. - We also share concerns regarding intellectual property and proprietary information being disclosed and subject to Public Records Requests. |
| <i>Email</i> | NW Cannabis Solutions, Becca Burhardi, Kelsey Holstrom | 9/29/2020 | <p>WAC 314-55-550</p> <ul style="list-style-type: none"> - (2) (b) is missing a key word - We have some general concerns with the vagueness of the language in (2) (b) (iv) - how is the Board confirming the information? How is the Board determining the reliability of a source? The science concerning inhaled additives is still new and is changing all the time, particularly in regards to public health; there is potential for incomplete information to be presented as conclusive. I would recommend changing this to read in a way that specifies the validity such as: “Other information sourced from peer-reviewed scientific literature, confirmed to be reliable and current by the Department of Health” - For (2) (d) thru (e), should producer processors expect a new vapor disclosure form every year? How are changes to the list proposed and confirmed & is there opportunity for public comment and stakeholder input during that process? Most importantly, how are changes to the list implemented in terms of compliance and how long will producer processors be given to make potentially drastic changes to their processes and their packaging? |
| <i>Email</i> | Lukas Hunter | 9/29/2020 | <p>Thanks for leading the listen and learn session today, as always it is wonderful to have the interactive experience with the industry and the WSLCB in the rulemaking process. From my prior email I would like to add, that when I look at this form I have been looking at reductions (I think that is rather clear from my comments), but where I would like to see things removed I see them covered in other sections of rule or policy. Transparency is paramount when it comes to public health and safety, and in the unfortunate event of sickness resulting from the consumption of these products finding the root cause it necessary. The two areas where I want to be cautious is in accidental public disclosure, and ease of filling out these forms.</p> <p>During the listen and learn a retailer even requested to have access to these forms to see what is in the products (directly in opposition of concerns around intellectual property safety) and this retailer along with all consumers should have access to this information per packaging</p> |

Public Comment — Marijuana Vapor Products

Attachment A – Written comment received following CR101 filing on July 8, 2020

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| | | | <p>and labeling rules. Further the safety and protection around the disclosure of intellectual property was a concern from the inception of this form last summer when we drafted the initial version. I would hope we can find a safe way for disclosure to take place without giving away our secret recipes that make our products unique to each company, what we referenced last summer was the federal requirement for ingredient disclosure for cosmetic products https://www.fda.gov/cosmetics/cosmetics-labeling/trade-secret-ingredients Then with the disclosure of additional documentation like Safety Data Sheets (SDS) or additional information that adds the requirement to attach additional documentation beyond the form seems it could be inaccessible with a variety of computer know how and there are already requirements from Lnl and WSDA to keep SDS on site for all chemicals/compounds that require a SDS. Without a requirement in rule to disclose this information and a requirement to keep these records on site per 314-55-1055 and further reinforced by WAC 314-55-087 (record keeping requirements) I see a lot of opportunity to remove line items from this form.</p> |
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Public Comment — Marijuana Vapor Products

Attachment B – Listen & Learn Session #1, Held September 1, 2020 re Conceptual Draft Rules WAC 314-55-010(4) and (40)

| Source | Commenter | Date Received | Comment |
|--------|------------------|---------------|---|
| L&L #1 | Lukas Hunter | 9/01/2020 | WAC 314-55-010 Subsection 4 - Replace “cannabis” with “marijuana” |
| L&L #1 | Crystal Oliver | 9/01/2020 | WAC 314-55-010 Subsection 4 - Strike second “noticeable” in definition |
| L&L #1 | Hailey Croci | 9/01/2020 | WAC 314-55-010 Subsection 4 – Add “aroma” after “taste” |
| L&L #1 | Chris Masse | 9/01/2020 | WAC 314-55-010 Subsection 4 – Concerned about how this definition works with the bill/ couldn’t reconcile the definition in the draft with the way “characterizing flavor” is used in bill |
| L&L #1 | Jaramie Thomas | 9/01/2020 | WAC 314-55-010 Subsection 4 – Should specifically include “botanical terpene” |
| L&L #1 | David Haldreth | 9/01/2020 | WAC 314-55-010 Subsection 40 – Believes it should start with terpenoids--at the top, and below that should be terpenes. The botanical terpene definition should cross out constituents. WebEx Chat from david heldreth to everyone: 2:33 PM s is flavoring rather than to act as a drug. This includes: (i) Terpenes derived from essential oil, which is natural oil typically obtained by distillation and possessing the characteristic fragrance of the plant or other source from which it is extracted; (ii) Terpenes derived from oleoresin, which is a natural or artificial mixture of essential oils and a resin; (iii) Terpenes derived from Distillate; or (iv) Any product of roasting, heating, or enzymolysis which contains only terpenes. (b) “Synthetic terpenes” means any terpene that does not occur in the cannabis plant, or in other botanical sources, and is produced through chemical manipulation in a laboratory or similar facility. (c) “Terpenoids” means the natural products and related compounds formally derived from isoprene units, or “isoprenoids,” that have the same meaning as that found in the current version of the International Union of Pure and Applied Chemistry (IUPAC) and as hereafter amended. |
| L&L #1 | Kelsey Holmstrom | 9/01/2020 | WAC 314-55-010 Subsection 40 – WebEx Chat from Kelsey Holstrom to everyone: 2:33 PM (40) (a) (iv) - Any product of roasting, heating, or enzymolysis which contains terpene.Should be plural "terpenes" |
| L&L #1 | Brad Douglas | 9/01/2020 | WAC 314-55-010 Subsection 40 – Incorporate the CFR by reference 21 CFR 101.22 instead of defining it separately WebEx Chat from Brad Douglass to everyone: 2:37 PM Botanical Terpenes = Natural Flavors. 21 CFR 101.22 WebEx Chat from Brad Douglass to everyone: 2:38 PM https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.22 |
| L&L #1 | Crystal Oliver | 9/01/2020 | WAC 314-55-010 Subsection 40 – For the list of items at the beginning: “spices, . . .” believes the order or the list should be modified Disagrees with the language “rather than act as drug” Question why “oleoresin” is included in the definition Question why “distillate” is included in the definition of “terpene” |
| L&L #1 | Chris Masse | 9/01/2020 | WAC 314-55-010 Subsection 40 – Recommend striking terpenoid, isoprenoid since those terms aren’t used in the bill |
| L&L #1 | Lukas Hunter | 9/01/2020 | WAC 314-55-010 Subsection 40 – Disagrees with the language “rather than act as drug” Disagrees with the language about “chemical manipulation” Would like to have a general definition of “marijuana vapor product,” will send that later |
| L&L #1 | Shawn DeNae | 9/01/2020 | Definition of “Harvest,” “lot,” and “strain.” Remove “strain” from the definition of “harvest” and “lot” |

Public Comment — Marijuana Vapor Products

Attachment C – Listen & Learn Session #2, Held September 29, 2020 re Conceptual Draft Rules WAC 314-55-550 and Marijuana Vapor Product Disclosure Form

| Source | Commenter | Date Received | Comment |
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| L&L #2 | Kelsey Holmstrom | 9/29/2020 | <p>WAC 314-55-550 - Science concerning additives is changing all the time. Potential for incomplete information to be presented as complete. Add something to specify the validity</p> <p>From chat bar: (2)(b) is missing a key word, I'm guessing it should be "data" (2) (b) (iv) How is the Board confirming the information? How is the Board determining the reliability of a source? The science concerning inhaled additives is still new and is changing all the time, particularly in regards to public health; there is potential for incomplete information to be presented as conclusive. I would recommend changing this to read in a way that specifies the validity such as: "Other information sourced from peer-reviewed scientific literature, confirmed to be reliable and current by the Department of Health" For (2) (d) thru (e), should producer processors now expect a new vapor disclosure form every year? How are changes to the list proposed and confirmed, is there opportunity for public comment and stakeholder input during that process? Most importantly, how are changes to the list implemented in terms of compliance and how long will producer processors be given to make potentially substantial changes to their processes and their packaging?</p> |
| L&L #2 | Lukas Hunter | 9/29/2020 | WAC 314-55-550 - Lack of definition behind "public health." Suggestion to add a definition to public health to the definition section in the chapter. Will email |
| L&L #2 | James McCray | 9/29/2020 | WAC 314-55-550 - No need for section on devices; should ban sale but not use. Can/how will the LCB regulate the use of a device? |
| L&L #2 | Kelsey Holmstrom | 9/29/2020 | <p>Disclosure Form - Q 3 under additives - what is a thickener? Distinction between botanically derived?</p> <p>Q3: Additives--alpha-bisabolol—could also be a terpene. How are these Botanically derived/ biological source—is there a distinction?</p> <p>From chat bar: NWCS also has concerns regarding proprietary information being disclosed, echoing Lucas's comment. In question #3 under the Additives heading, Alpha bisabolol is listed as a thickener; it is also a common terpene – how is the LCB determining which terpenes are considered thickeners and why is alpha bisabolol listed here? #4 & #5 under the Additives heading – #4 reads "Do you flavor your product with terpenes derived 'directly and solely from marijuana as defined by RCW 69.50.101, hemp plants grown and tested by state law, or from another biological source" and #5 reads "Do you flavor your product with botanically-derived terpenes" I don't understand the distinction between these questions; they appear redundant. Under Additives currently prohibited heading, #1 asks if the vapor product is flavored with "synthetic terpenes or essential oils" – however, essential oils is listed under the LCB's definition of "botanical terpenes" which are permitted, so it does not appear accurate to disclose them under the prohibited heading.</p> |
| L&L #2 | Lukas Hunter | 9/29/2020 | Disclosure Form - Applicable to all mj concentrates for inhalation; concern regarding public disclosure of ingredients. Not just applicable to "MJ Vapor Products" –rule language uses "MJ Vapor Concentrates." Expand to "MJ Vapor Concentrates" How will the form be protected from public disclosure? Very sensitive data included on the form |
| L&L #2 | Crystal Oliver | 9/29/2020 | Disclosure Form - Concern over proprietary nature of products |
| L&L #2 | Jamie Shipman | 9/29/2020 | Disclosure Form - Can retail stores obtain these lists? Not currently available. Would this form/ collected data be something retail stores could have access to? Would be helpful |
| L&L #2 | Lukas Hunter | 9/29/2020 | <p>Disclosure Form - Specific to a batch, thus required to be filled frequently. Highly redundant and cumbersome. Remove source of cannabis. Remove additives currently prohibited.</p> <p>This form has to be filled out quite a few times. This is going to create a lot of redundancy if we have to fill this out from every new distillate. Lukas is up to 312 submissions already</p> <p>The location of a distributor is sometimes proprietary information</p> <p>"Additives currently prohibited" section is not necessary, creates a length to the form that is unnecessary</p> |

Public Comment — Marijuana Vapor Products

Attachment C – Listen & Learn Session #2, Held September 29, 2020 re Conceptual Draft Rules WAC 314-55-550 and Marijuana Vapor Product Disclosure Form

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| L&L #2 | Hailey Croci | 9/29/2020 | Disclosure Form - Anything regarding heating devices or testing of devices? Depending on the heating range of the devices, could interact differently with the ingredients |
| L&L #2 | Crystal Oliver | 9/29/2020 | Disclosure Form - Possibly separate form for hardware? When does this form, and how often, does form need to be submitted? For each strain? Clarify and simplify. Suggest separate form for hardware. Clarification on when the form is to be submitted/ how often it should be submitted? Submit one for each strain of the product seems excessive. Take a look and see if it can be clarified or simplified. |
| L&L #2 | James McCray | 9/29/2020 | Disclosure Form - Conceivable that an ingredient could be "bad" from one supplier but not others. Responding to the comments about distributor information being proprietary: Ingredient could be bad from one supplier and not from others, so this information is important in the event that there are recalls. Balance the consumer/ public health and safety with interest in protecting proprietary information |