From:	John Thompson
To:	OLCC.Rulemaking * OLCC
Subject:	Additives Rule Package Public Comments
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Here you go:

Best,
JT

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Sublime Solutions Additives Rule Public Comments

Submitted 11/18/2020

My name is John Thompson, I own and operate Sublime Solutions, a contract processor in Eugene. Many of our clients have us manufacture products that will be effected by this new additives rule.

I have been intimately involved with this rules process from the start earlier this year. In doing so, I have become a facilitator and liaison for a broad range of interested stakeholders including

- licensee's in every category,
- high quality ingredient manufacturers who currently supply Oregon's market
- and industry legal and lobbying groups.

The process has been somewhat contentious, particularly in the initial stages, this is due to the logistic and technical challenges this complex issue presents along with the major differences between the agency and industry in terms of a preferred solution.

That said, after quite the roller coaster ride many of us have experienced, over the past couple of months, due to a lot of hard work and a more open, collaborative process between the agency and concerned stakeholders, I truly believe we can and will end up with a rule that will work for everyone. A rule that is grounded in

- the best current information,
- reasonable logic which respects the needs of all effected parties and
- accomplishes the fundamental goals of
    - providing the agency what it needs to properly regulate Oregon's cannabis supply chain,
    - giving the consumer an unprecedented amount of information to make their product choices and
    - the industry the ability to continue providing these products which many consumers want and prefer, with as much confidence as is currently possible that there are minimal risks.

The suggested modifications that we have submitted assure that high quality, insured ingredient manufacturers can and will continue to supply the Oregon market. At the same time, they will create a significant barrier for uninsured "fly by night" type ingredient suppliers and also insure that off the shelf food additives are not approved for use. It will basically insure, to the best of our current abilities, that

- the "good guys" remain in the Oregon supply chain and
- that less desirable manufacturers are disincentivized and
- inappropriate products are not allowed.

This can and should turn out to be a truly a win-win situation for agency and all those businesses who are working with integrity and dedicated to doing the right thing for their customers. If this outcome occurs, the current rules process, particularly over the past couple of months, should become an example and template for how future rules making should occur. This holds particularly for rules with such high levels of logistic and technical challenge and divergent opinions as to how write and implement them.

This is what I and those I represent have worked in good faith to accomplish and I have confidence the agency will do the right thing and support our revisions in the final draft rule.

Over two years ago, during labeling rules changes, I began to suggest that a more robust ingredients review process be instituted by the agency. This was discussed a number of times with agency staff who liked the idea, but due to many considerations and other priorities, it was never formalized.

Now that the need for such a process is clear and upon us, I think, *if our suggestions are incorporated*, this first rule specifically addressing the issue is a very good starting point. In the case that these suggestions are not incorporated and this current draft language is adopted, it will create a de facto ban for many licensees and quality additive manufacturers, therefore significant and unnecessary damage will ensue.

This rule also has a high likelihood of setting some level of national precedence. *If the suggested modifications are incorporated*, I believe both the agency and industry can feel very satisfied in the results and the fact that once again Oregon can claim to be one of the best, most progressive programs in the nation.

I've heard the agency has not gotten many comments, as of last week. This is somewhat hard for me to understand, given the agencies reasonable estimates that this will effect 5-10 % over the products in the market and near 60% of all processor, wholesaler and retail licensees.

I chalk it up in part due to the fact that roughly half of the licensees out there have come to the conclusion that a full ban is coming, so why expend time and effort arguing about it.

This observation is based on numerous comments by licensees that my sales team has talked with in the recent past.

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Below, I have excepted the necessary sections of the "Notice of Proposed Rulemaking, including Statement of Need and Fiscal Impact" and redlined our comments and suggested language changes.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(a) Estimate of the number of small businesses subject to the proposed rule and identification of the types of businesses and industries with small businesses subject to the proposed rule:

Based on activity recorded in the OLCC's Cannabis Tracking System, OLCC estimates that approximately 140 processors and wholesalers have manufactured and/or transferred inhalable cannabinoid products with non-cannabis additives. Of those businesses, OLCC estimates that 111 are small businesses.

For better perspective, this equates to 33% of all processors and wholesalers in general and 24% of the total are small businesses.

OLCC estimates that 624 active retailers have made sales of inhalable cannabinoid products with non-cannabis additives since March 2020. Of these, OLCC estimates that 534 are small businesses.

This is 90% of all retailers, with 75% of the total as small businesses.

OLCC further estimates that approximately 12 third-party additive companies would be affected by this rule. OLCC does not have information of how many of these businesses qualify as small businesses, or how many are based in Oregon.

In total, OLCC estimates that approximately 657 small businesses may be impacted by this rule.

Excluding producers and laboratories, which based on the numbers above looks like what how the math works, this is 58.5% of the total active processor, wholesaler and retailer licensees.

(b) Brief description of the projected reporting, recordkeeping and other administrative activities required for compliance with the proposed rule, including costs of professional services:

OLCC estimates the following costs of compliance for the new rules:

The ban on certain ingredients such as MCT oil, as well as the possibility that some third-party manufacturers may be unwilling or unable to comply with the new standards for non-cannabis additive ingredients, may result in OLCC processors substituting towards cannabis-derived terpenes and other ingredients for their inhalable products. OLCC estimates that non-cannabis additives are 30% the cost of cannabis-derived terpenes. Licensees typically include these ingredients at a 5-10% rate in the final product. OLCC does not have sufficient data on the full cost of input materials and therefore cannot estimate the increase in total production costs.

A reasonable guestimate is a minimum cost increase of 10-15% to switch to cannabis derived terpene blends (CDT's), which is significant. The reality will likely be higher. What is missing here, based on last year's emergency ban, is that the cost of cannabis-derived terpenes (CDT's) will increase due to increased demand and the fact that there are not enough providers nor volumes of CDT's to fill the gap if botanical terpene blends (BDT's) are not available.

As the current draft language stands, it creates a de-facto ban, therefore we can anticipate both a shortage of and cost increase for CDT's in the supply chain. It is not likely that this would change very quickly given that CDT's cannot be bought from out of state sources and many producers of CDT's use them for inhouse manufacturing, not to sell them on the open market. If their product lines are successful there is a clear disincentive to selling their CDT's to competitors. In this likely scenario, licensees who use BDT's lose these product lines and revenue, at least temporarily, for many quite possibly permanently. If they have the resources and desire they will have to invest in inhouse CDT production to replace their existing product lines in cases that this is even possible, given the extreme difficulties of matching the product profile when switching from one to the other.

Submission of new item labels for approval under the revised rules would cost $100 per item. Under OLCC's rules, multiple "flavors" or variants of the same item could be submitted under a single application. OLCC does not have data indicating how many individual label applications would have to be submitted, but estimates that the cost of compliance would be approximately $1,000 per affected business.

Revisions of new labels and (optional) label inserts to meet ingredient disclosure requirements would also be required, although OLCC estimates that only minor revisions would be required. OLCC estimates that costs of graphic design would range between $50 and $100 per hour. Because the revised rules require a slightly modified product identity, additional information within an already designed and approved ingredient listing, and/or disclosure of the full list of ingredients on an item insert that is likely to be standardized (and/or have fewer design elements than exterior packaging), OLCC expects redesigns to be minimal. OLCC has no way of firmly estimating the average time it will require for design revisions to be made, but a full day of a graphic designer's time would potentially cost between $800 – $1,000.

Adding a list of 20-60 individual ingredients, in the case of BDT's, to a label is not a minor revision in any way shape or form considering that both the packaging and labels for most vape cartridges are quite small and in many cases the "real estate" is already quite cramped. Thus, resizing the packaging/labels may be necessary. Some of the current packaging on the market does not lend itself easily to adding an insert either.

Therefore, many licensees will have to spend significant time and money redesigning and revising their existing packaging. The assessment above vastly downplays both the significance of the challenge and the potential costs, which the agency states it has no way to estimate. OLCC expecting the redesigns to be minimal, and seemingly implying that a day's work by a graphic designer might be enough, shows that the agency doesn't have much of a realistic understanding of this aspect of the industry. These statements are a definite speculation on the agencies part, and not estimations that are very accurate, nor applicable, in any broad or generalizable sense. There will likely be a lot more involved than just "minimal" graphic redesign in many if not most cases. A full redesign and size changes entail new dies being cut, and can cause a number of design loops before new packaging can be manufactured.

A web based option for consumer disclosure should also be allowed.

The revisions may also require licensees to order and/or design new packaging. Existing items that are currently non-compliantly labeled but have compliant labels approved prior to July 1, 2021, will also require staff time to replace old labels with new labels (and possibly also ingredient inserts). OLCC has no way of firmly estimating the average time it will require for these revisions to be made, of the cost of new packaging or labeling, or of the labor cost of applying new labels. OLCC estimates that approximately 344,000 affected inhalable cannabinoid product units are in the inventories of 603 small business licensees, or an average of approximately 571 units per license. OLCC estimates that the labor cost to replace labels for this many units would likely be 40 to 80 hours of total staff hours; at a rate of $25 per hour this would be labor costs of $1,000 to $2,000.

This estimate is way off base. Using averages like this is extremely misleading. This activity will be almost totally on the shoulders of the 111 small business processors and wholesalers mentioned earlier, not the 603 small business licensees stated

here. It is highly unlikely that any retailers will take on this responsibility. Using the more reasonable licensee estimate of 111, the approximate number of units per license would average 3,099. Even this is somewhat misleading as these products are a much larger % of some licenses product lines than others.

The onset of the rule is February 1, 2021, and the sell-down period for previously approved inhalable cannabinoid products with non-cannabis additives is a further six months. The OLCC estimates that this amount of time will be sufficient for licensees to redesign labels and order/design new packaging. The sell-down period will also provide licensees an opportunity to sell existing stock of items in order to minimize both the number of inhalable cannabinoid product units and excess non-compliant labels that must be disposed of, as well as the amount of staff hours required to relabel items with newly approved labels.

The onset and sell through dates of the rule should be pushed back three or four months based on the following:

- Most licensees will want to have new compliant packaging/labels approved before continuing production of the products in question. A smart business decision.
- With the likelihood that the final draft language of this rule won't be finalized and published until December, and if it were on the 1st, that only leaves two months to revise, or worse redesign, packaging/labeling, submit this for approval, receive approval and order and receive the new packaging/labels. Due to occurrences outside the licensee's control such as delays with their packaging/labeling vendors, or labeling approvals, it may take significantly longer than 8 weeks to get through the process.
- If this cannot be accomplished within that time frame, the licensee may suffer a discontinuity in their supply chain due to having to pause manufacture of the product for a significant amount of time. This will have unnecessary negative impacts to their business through no fault of their own, excepting making a good business decision, i.e. getting the product registered as compliant via the packaging and labeling approval process before continuing to produce it.
- Given that there has not been any correlation whatsoever between BDT's and EVALI, there have been no reported cases of EVALI this year involving Oregon's regulated market and the agency is continuing to allow these products in the market with better oversight and labeling, there seems to be no need to rush the implementation date. A date that has a high potential for causing unnecessary negative impacts to licensees who provide and sell these products and the consumers who choose to buy them.

Another important, pragmatic aspect of any necessary relabeling, if it were to occur, is that OLCC should be very clear with retail licensee's that if a product needs relabeling, it should be returned to the licensee that it came from for relabeling and is not automatically and forever uncompliant product. This will help avoid situations that may cause confusion, negative impacts to the relationship between retailers and the brands/processors that supply these products and unnecessary financial impacts.

OLCC licensees will be required to re-categorize existing items by February 1, 2021. OLCC expects minimal time or cost impacts to licensees, because licensees will have sufficient lead-time to begin categorizing items under the correct category as they are created. OLCC estimates that approximately 603 small business licensees have an inhalable cannabinoid product with non-cannabis additives in inventory as of October 20, 2020, and that there are approximately 22,446 such "packages" in the Cannabis Tracking System in the possession of small business licensees. RFID unique tags are required for all "packages" in the Cannabis Tracking System, and each tag costs $0.25; if all such packages were to be re-categorized, the supply cost per license would be approximately $9.50. Labor cost is more difficult to estimate, but it is likely that staff time of re-categorization would take approximately 8 to 40 staff hours; at $25 per hour this would cost between $200 and $1,000.

Again, this is a highly speculative and misleading estimate for the reasons mentioned above about using improper generalized averaging across licensees vs. the reality of a wide variance in the amount of products that any given licensee will be dealing with in this regard.

Why not just simplify it and allow existing product to remain in CTS as is for the duration of the sell down period, *if* it was manufactured before the implementation date, at which time IF it is still on the shelf it would be returned for relabeling and updating on its formal item type in the system. This would save time, cost, confusion and aggravation for everyone involved. I just don't see any real gain in forcing this re-categorization of any existing product by implementation date. They will easily sunset out of the system by the end of the sell through period if not before then, or as mentioned be able to be returned to the appropriate licensee for relabeling and recategorization.

I know I'll start using the new CTS categorization for new batches as soon as it's available. Hopefully, that will be shortly after the final draft is published, if not concurrently. I imagine most processors and brands will do the same, as it's best approach.

I see neither the need nor the logic of this re-categorization exercise, but anticipate negative impacts resulting. It seems a logistical request that is not necessary in terms of accomplishing the fundamental goals for these new rules. The move of BDT vape products from the extract category to combined category is a real life example of the problems this can create. Why add more hassle and cost for everyone when it's not necessary?

For third-party manufacturers, OLCC estimates that the direct cost of compliance would be minimal to negligible. Third party manufacturers presumably already have knowledge of their own input ingredients and concentrations. Many, if not most, of these ingredient lists are already provided to OLCC processors under a non-disclosure agreement. The only requirements of these rules would be a prescribed format of these ingredient lists, including full disclosure of ingredients; maximum concentrations of each; and labeling of intended use of the additive including use in an inhalable product. In cases where these ingredient lists already disclose all ingredients and concentrations, the only direct cost would be inclusion of the intended use. For ingredient lists that do not currently disclose all ingredients and/or maximum concentrations, the creation of the ingredient list should be minimal, because the OLCC revised rules would allow electronic documentation to be provided to OLCC licensees and submitted as part of the item label pre-approval application.

The third sentence of this paragraph is patently untrue. I have been working with flavor vendors for years and not done this. Many, if not most, of the licensees I know can likely say the same. A comment during the recent RAC from Kurt Metros, of Extract Consultants, mentioned that with *some* of his clients this is the case. In general, flavor manufacturers hold their recipes very close to the chest for good reason, and NDA's when respected are effective but are very difficult to enforce. They are more a gesture of good faith, which only adds to a flavor manufacturer's caution in this regard.

To generalize those comments in the fashion is very inappropriate. It gives the illusion that this is standard practice. This further erodes my confidence in the statements made by the agency throughout this process and in this narrative supporting the current draft language, which seems to consciously downplay the costs, logistics and negative effects of the current language.

The requirement to add the "intended use" statement the way it is currently language creates a de-facto ban, which the agency is definitely aware of. This clearly goes against the intent of the directives laid out in the recommendations from the Governor's vape task force.

This requirement, which is not necessary to accomplish the fundamental goals of the additives rule, is actually counter-productive in terms of the primary goal of protecting public health and safety. This is due to the fact that it may potentially cause, not just a significant cost increase for flavor manufacturers, but the eventual loss of their product liability insurance and therefore a large part of the consumers financial safety net in terms of payout funds available for damages in the case of an adverse reaction which can be traced back to the use of the flavor additive at some point in the future.

In discussing with agency staff as to the functional reasoning for this requirement, the only answer was to insure that the ingredient manufacturer was liable in case of an adverse event. It seems clear that this is not actually a significant problem, and instead this requirement is included to discourage ingredient providers from selling into the Oregon market. Here's why:

- The agency clearly knows that this requirement will cause many if not most ingredient manufacturers to leave the Oregon market. They have stated this on the record during the rules advisory process.
- The ingredient manufacturer's and the licensees who utilize these products both share liability in the case of an unforeseen adverse event, and this liability is primarily on the licensee who chooses to make final products with these ingredients.
- Both the licensees and ingredient manufacturers clearly know that these ingredients have been developed primarily for use in inhalable products. Both parties are on record with the agency discussing it. Therefore, the idea that a standard disclaimer on the manufacturers' SDS, and the absence of the required "intended use", would provide any true protection in a court of law seems absurd. In fact, in such a case, damages for an unforeseen adverse event may even be higher, which in fact would help any consumer effected more so in terms of financial ability to overcome.
    - The manufacturers are clearly creating many of these formulas based directly on the chemistry expressed in the cannabis plant and name their blends to indicate which strain the formula is at least in part mimicking. Some of them actually do clearly indicate this potential use on their websites and in conversations with their clients, and some recommend usage levels.
    - There are now cases being litigated in the nicotine e-juice arena that clearly show the disclaimers some manufacturers have on their SDS's will not shield them from liability claims.
- It seems clear that any licensee carries the primary liability for unforeseen adverse events involving their products. Due to this, I personally have done serious diligence and risk assessment on the ingredients we use and the suppliers.

Obviously, I like many others, feel the relative risk is low and similar if not identical to the use of strictly cannabis derived products. There is currently no scientific data or information to show otherwise.

- The ingredient manufacturers, at least the ones I have been involved with, have also done their diligence and risk assessments based on best current data, are willing to take the liability, as they know if it went to court they would not avoid some level of liability. This is why they have invested in already expensive insurance and do not want to lose it based on an unnecessary requirement like the one in question here.
- The clear reason they will not fulfill this statement of "intended use" requirement, is not to avoid liability, but to be able to have proper insurance IF an unforeseen and unintended adverse event were ever to occur. This type of product liability insurance is far more expensive than for many other industry's products, due to the fact that cannabis is a very new industry and research into these issues has only begun. This is true in general for cannabis product liability insurance.

Therefore, the only functional result of this requirement seems to be to keep these ethical, quality manufacturers out of the Oregon supply chain, i.e. a de facto ban. This requirement does not further public health goals, nor does it aid in the agencies need to understand what ingredients are in the Oregon supply chain nor it's ability to track and trace them if necessary in the case of an unforeseen adverse event at some future date.

With the modifications suggested herein, some of the quality flavor manufacturers will be willing to comply AND it will allow the agency a far better ability to ensure that off the shelf food flavors/ingredients will not make it into the supply chain.

For third-party manufacturers, there may be indirect costs of these rules related to increased cost in product liability insurance premiums as a result of being required to state that the additive's intended use is in inhalable products. OLCC has no way of estimating these indirect costs; OLCC rules also do not require that third-party manufacturers hold product liability insurance.

Given a primary goal of this rules process is the creation of a reasonable framework that allows OLCC to know what ingredients are in the industry's supply chain, have the ability to track and trace those ingredients when necessary and assure public health is properly addressed…why wouldn't you want to take steps to assure, even though indirectly, that most ingredients were created by ethical, scientifically based manufacturers backed up with proper insurance, instead of writing a rule that endangers that outcome, and may lead to primarily uninsured, lower quality manufacturers supplying the market who may say anything to make a buck and scoop up market share abandoned by the kind of manufacturers that most licensees and consumers would obviously prefer?

The fact that OLCC does not require third-party manufacturers hold liability insurance, does not mean that the agency should disregard the importance of this for stakeholders and consumers.

OLCC expects no effect on the cost of compliance due to the change in definition of the term "licensee." The change to the definition of "licensee," in isolation of any other changes to relevant sections of rule, merely clarifies the status quo definition. It is not expected to have a cost of compliance because the persons who qualify as a licensee under the new definition are identical to the persons who qualify as a licensee under the previous definition.

(c) Identification of equipment, supplies, labor and increased administration required for compliance with the proposed rule:

OLCC does not anticipate ongoing equipment, supply, labor, or administrative costs of compliance due to these rules. The costs of compliance described above pertain to the costs to come into compliance and remain in compliance with these rules.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

OLCC began this rulemaking process by holding a rules advisory committee comprised of subject matter experts and public health officials. OLCC then held two rules advisory committees that included OLCC licensees and third-party additive manufacturers. Discussion from the second rules advisory committee informed revisions to the proposed rules, which significantly scaled back fiscal and economic impacts to licensees. Revisions to the proposed rules were presented to the third rules advisory committee, which was comprised of small businesses that would be directly affected by the proposed rules. Discussion from this third rules advisory committee informed further revisions to the proposed rules to further decrease the fiscal and economic impacts to small businesses as well as dramatically reduce the costs of compliance. The OLCC also developed these rules based on input from Oregon Health Authority and Alcohol and Drug Policy Commission staff related to possible health impacts. This was done by developing and completing an analysis of possible public health impacts.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

AMEND: 845-025-3220

RULE SUMMARY: The rule is being updated to prohibit processors from manufacturing inhalable cannabinoid products with non-cannabis additives that do not meet the updated requirements of this rule package, but also provides a limited sell-down period of these products that are manufactured prior to February 1, 2021. In an effort to further strengthen OLCC's ability to protect the public health, the rule is being updated to remove the limitation that adulterants can only come from non-cannabis sources, and broadened the applicability beyond "additives" to include substances.

See comments above in the Cost of Compliance section relating to implementation and sell through dates. We strongly suggest pushing the dates back 3-4 months.

CHANGES TO RULE:

845-025-3220
General Processor Requirements ¶

(~~3~~d) If such an item is an inhalable cannabinoid product that does not meet the requirements in OAR 845-0253265, except that a processor may transfer or sell an inhalable cannabinoid product that does not meet the requirements in OAR 845-025-3265 until ~~July~~ October 1, 2021, if the non-compliant inhalable cannabinoid product was processed prior to ~~February~~ May 1, 2021.¶

ADOPT: 845-025-3265

RULE SUMMARY: The proposed rule creates additional requirements in order to better protect public health and safety by ensuring that all the contents of non-cannabis additives for use in inhalable cannabinoid products are disclosed to regulators. All non-cannabis ingredients must be clearly stated to be intended for human inhalation. Further, the rule sets prohibitions upon certain ingredients being used in inhalable cannabinoid products that are most likely to cause harm when exposed to cannabis vaping conditions and inhaled.

Rational for the redlines below can be found in my redline comments in the related section regarding the Cost of Compliance.

The companies that provide additives to OLCC licensees are not overseen by state or federal regulatory authorities for products meant for inhalation. The additive ingredients may be "Generally Recognized as Safe" (GRAS), but GRAS certification is scientifically evaluated only based on use in food products that will be ingested. An ingredient's GRAS status is irrelevant for the question of whether it is safe to vaporize and inhale. Many of the non-cannabis additive products purchased by OLCC licensees have unknown health effects when used in cannabis products that will be vaporized and inhaled.

Many of the non-cannabis additive products, i.e. BDT flavor blends, are designed to match the chemical profiles found in cannabis, using the same molecules found in the plant and therefore can be assumed to have the same potential health effects, positive, neutral or negative, that come from equivalent cannabis derived products and ingredients.

Currently, many non-cannabis additives used in these products contain ingredients that are not disclosed to OLCC, retailers selling the products, nor consumers purchasing the products. Without full disclosure, regulators cannot begin to assess the safety of these ingredients and consumers cannot make an informed choice about what they are consuming. These rules also require the maximum concentrations of non-cannabis ingredients within additives to be disclosed to OLCC so that if an ingredient is found to be problematic in certain concentrations, the OLCC can take measures to prohibit or limit its use.

As of this rulemaking, most of the manufacturers of non-cannabis additives utilized in inhalable cannabinoid products state that their products are meant for culinary use and make no claims that the ingredients should be inhaled.

However, these same additive companies market their products almost exclusively to the cannabis industry for usage in vaporization products. Many companies add disclaimers related to their additives products' use for inhalation and some go so

far as to put the onus on the end-user to conduct safety assessments. The requirement set forth in this rule for the clear labeling of intended use of human inhalation will make explicit to OLCC licensees which ingredients should be used in inhalable products and which cannot be.

OLCC licensees are already aware that these flavor ingredients are sold for use in cannabis and buy them for that purpose. The addition of this requirement is not necessary for this to be clear and the lack of that statement does not indicate that a flavor blend cannot be used for this purpose.

Most of the quality manufacturers of these ingredients have done risk assessments as they develop these products, base on the best current data available. To imply otherwise is myopic at best. They are not maliciously, or otherwise, consciously "putting the onus" of safety assessment on the consumer, if by "end user" you mean consumer, but this is what the statement seems to clearly imply, i.e. they are trying to "pull a fast one" and avoid any/all liability for use of their product…which is absolutely not true of the high quality vendors I know and work with.

If they are putting this onus on anyone, it is the licensee who is assessing whether they will choose to use the ingredient in their final products. If by "end user" you are referring to the licensee using the ingredient, then it is somewhat appropriate that they do a decent risk assessment. This is the way it works in many industries (I have worked in both the dietary supplement and food industries, wherein very similar situations occur). Both parties need to do their own proper diligence and risk assessments before deciding on how to formulate their products.

The concerns about liability issues, which the agency has shared with me, are addressed in earlier comments.

In the United States, 2019 saw an unprecedented outbreak of e-cigarette, or vaping product-use associated lung injury (EVALI), which sickened thousands and killed hundreds due to acute lung injury. Oregon had 23 confirmed cases, 2 of which were fatal. Primarily, EVALI patients have been diagnosed with lipoid pneumonia (inhalation of oil) and/or chemical pneumonitis (chemical burns in the lungs). The precise causative agent of EVALI is still unknown and may never be known due to the many variables and complex chemistry that occurs in vaping products. Researchers have speculated that several factors may be responsible, including cutting agents, flavorings, and pesticides. Research has shown that certain substances, when heated under common cannabis vaping conditions and inhaled into the lungs can have serious negative health consequences. Therefore, the OLCC is proposing to explicitly prohibit the most troublesome substances and will take action should more research arise.

OLCC is right, and industry agrees, that know harmful substances should be banned. Many stakeholders have been surprised at the removal of the requirement for at least an initial assay for these substances when a licensee submits information for the additive via the label approval process, and I would suggest the addition of language that clearly states the agency will spot check this at it's sole discretion moving forward.

It is clear that far and away the most highly correlated vectors of the EVALI crisis are Vit. E Acetate, and heavy metal fumes from cheap vape cartridges, used primarily in the black market…on top of that it seems reasonable to assume high levels of pesticides in those products may have been a serious compounding factor.

Outside of minor speculation, BDT flavor blends in cannabis products have no known documented correlation with the EVALI crisis anywhere. As mentioned before they are comprised of many, if not mostly or totally, of the same compounds found in cannabis. Therefore there is a reasonable level of equivalency between these formulations and CDT's in terms of potential health impacts. In fact, at this time, far less is known about what the exact make up of CDT's extracted from cannabis is, compared to engineered BDT blends.

I think it's very unfair to demonize and make a "boogie man" out of BDT's, and clearly imply that the providers are less than ethical, with no factual basis to support this perspective. Based on current knowledge and data in fact, it seems like there is a strong argument that this perspective is way off base.

CHANGES TO RULE:

<u>845-025-3265</u>
<u>Inhalable Cannabinoid Product Processor Requirements</u>
<u>(1) A processor may only use a non-cannabis additive in an inhalable cannabinoid product if the non-cannabis additive is accompanied by a list of ingredients from the manufacturer of the non-cannabis additive that:¶</u>

(a) In a header section, displays the name of the non-cannabis additive and the business name of the manufacturer of the non-cannabis additive;¶

(b) In clear and legible font, includes a statement that ~~each of the ingredients in~~ the non-cannabis additive is for use in a product intended for human inhalation;¶

In general, intended use statements and instructions are for the product being sold, not each individual ingredient or element therein. This change is in alignment with standard business practices and makes the most sense. If a manufacturer is willing to make a use statement it is for the whole product, and implies that the product as a whole was created for the stated use. It seems unduly burdensome and very unusual to require a specific statement for each ingredient within the final product.

Due to the logistics that may be involved and the unusual nature of this detail, the quality flavor manufacturers I have consulted with will not comply if this language is finalized. If, on the other hand, they can make the reasonable and standard claim that their product, as a whole, is being sold and intended for use in inhalation products, they will be able to comply.

In doing so, they may also add recommended concentration ranges, and potentially temperature ranges, to aid licensees in proper use. They may also add a statement that these products have not been evaluated or approved inhalation by the FDA or any government agency. This is a true statement, and again only heightens the awareness on the part of licensees that proper risk assessment and a clear decision to take on liability are business decisions that they need to seriously consider and consciously chose to take on. I think these are two highly desirable outcomes for all parties concerned, therefore the allowance of such statements should be granted by the agency when receiving the required documents.

(c) Accurately identifies all ingredients in the non-cannabis additive; and¶

(d) For each ingredient of the non-cannabis additive, includes:¶

(A) A Chemical Abstracts Service Reference Number that specifies the ingredient's isomer and, if applicable, enantiomer; and¶

(B) ~~The ingredient's maximum concentration within the non-cannabis additive.¶~~ A list of ingredients with each ingredients range of concentration that at the request of the licensee has been submitted by the manufacturer to the agency during the label approval process for the licensee's product.

The actual concentrations of ingredients should only be required to be submitted directly to OLCC and held in confidence under trade secret protection. Otherwise, a licensee can just steal the formula, or an employee may walk off with it. The licensee intending to use the additive only needs a basic list for consumer disclosure use on, or in, the final product's packaging. The flavor vendors I have worked and consulted with as a general rule *do not* share the ingredient decks, and in cases where they do, an NDA is required and the deck does not usually reveal the actual %'s used.

A simple mechanism to accomplish the direct, trade secret protected submittal to OLCC is redlined into the Packaging/Labeling Approval process language below.

The agency knows from previous input and comments at the last RAC, that this requirement would create an environment that flavor manufacturers would rightful refuse to sell in to. This requirement, especially in combination with a few others, creates a de facto ban. Many licensees would be significantly damaged by their suppliers reasonable unwillingness to comply, and would have a difficult time at best figuring out how to recover from this.

This is not functionally necessary to achieve the fundamental goals of this rule set as defined in the Gov.'s recommendations.

(2) A processor may not use a non-cannabis additive in an inhalable cannabinoid product that contains any amount of:¶

(a) Squalene;¶

(b) Squalane;¶

(c) Vitamin E Acetate;¶

(d) Triglycerides, including but not limited to Medium-Chain Triglyceride (MCT) Oil; or¶ (e) Propylene Glycol.¶
(3) On or after ~~February~~ May 1, 2021, a processor may not manufacture or process an inhalable cannabinoid product that does not meet the requirements of this rule.¶
(4) On or after ~~July~~ October 1, 2021, a processor may not possess, sell, deliver, transfer, transport, purchase, or receive an inhalable cannabinoid product that does not meet the requirements of this rule.¶ (5) Sanction.¶
(a) An intentional violation of this rule is a Category II violation.¶ (b) An unintentional violation of this rule is a Category III violation.
Statutory/Other Authority: ORS 475B.025, 475B.232, 475B.236 Statutes/Other Implemented: ORS 475B.025

ADOPT: 845-025-3270

RULE SUMMARY: This proposed rule requires that licensees possessing inhalable cannabinoid products with non-cannabis additives track these items in the cannabis tracking system (CTS) under a new category. Also, the rule requires that licensees record the additive name(s) and manufacturer(s) in these items in a way that matches the information on the additive's required list of ingredients. These two requirements will provide the OLCC with greater line of sight to which specific non-cannabis additives are on the market and in which items. This enables swifter action by OLCC if information emerges that calls the safety of an additive ingredient into question.

The requirement that the ingredient manufacturer's name be listed in the CTS is not necessary and in fact can cause damage to both the licensee using the ingredient and the ingredient manufacturer. The agency is clearly aware of this potential as it was discussed at the most recent RAC meeting. It seem a bit suspicious that this was not a requirement in the previous draft of the rules language and has now been added, unless part of the agencies agenda is to discourage flavor manufacturers from participating in the Oregon market, i.e. another requirement that aids in the creation of a de facto ban.

The "line of sight" and ability to quickly track and trace when necessary can easily be accomplished via other means.

What this requirement has a high potential of doing is seriously damaging a licensee's competitive edge. It also once again creates for the flavor manufacturer a threat to their competitive advantage due to the possibility of a short cut to back engineering of their product by those who wish to do so. Here is a reasonable example which elucidate this possibility, especially given the small and hypercompetitive market that Oregon has:

- A brand spends time and money developing a successful product using a particular flavor and builds significant market share.
- They are on the shelf in a dispensary, or better yet a dispensary chain, which has an in-house brand with an equivalent product. But the in-house brand, doesn't sell nearly as well.
- If this requirement remains in the final rule, the dispensary owners can now simply open up METRC and find out who the successful brand gets the flavor from, purchase it and undercut the price of the successful brand and/or remove the brands product from their shelves altogether.
    - The dispensary makes more margin, while selling at a lower price, on the in-house version of the product and can capitalize on the investment made initially by the successful brand by stealing the brands clientele.
- Some brands will purposefully use a their own trade name to help avoid similar problems, but the ease of a competitor with access to the actual flavor's manufacturer name serious damages this type of protection. I'm assuming the required name in CTS is the manufacturer's name for the flavor, not the brand's chosen trade name, so any level of protection via this practice will be nullified by this requirement.
- Unless the successful brand has exclusivity on the use of the flavor in Oregon, which is rare, this disclosure requirement has the potential to damage their competitive edge, and in this example remain in certain retail outlets.

The suggested change to use the Label ID# and license # of the licensee that "owns" the label, instead of the flavor manufacturer's name in the CTS. This allows the agency basically the same line of sight and quick track and traceability, due to the fact that the License # & Label ID# can quickly be used to reference the licensee/brand that the product came from, the ingredients list for the additive and the manufacturer of the additive. It also protects the licensee using the ingredient from potential problems like the example above.

Therefore, due to the potential damage of this requirement and the ease with which the agency can access the necessary "line of sight" and track and trace tools…this requirement is not necessary.

The inclusion of the additives name also seems unnecessary if the Label ID#/Licensee # is used in CTS, though this inclusion doesn't posse near the potential problem that the manufacturers name does.

Also, if there were more than one non-cannabis additive in a product, using the Label ID#/Licensee # strategy will reduce the amount of data necessary in METRC, which is generally a good thing…less room for entry error and less data in the data base. So, another added benefit of the suggested revision.

CHANGES TO RULE:

845-025-3270

CTS Requirements for Inhalable Cannabinoid Products with Non-Cannabis Additives

(1) On and after ~~February~~ May 1, 2021, any inhalable cannabinoid product possessed by a licensee, research certificate holder, or hemp certificate holder that contains a non-cannabis additive must be recorded in CTS:¶ (a) With the item category of:¶

(A) "Inhalable Cannabinoid Product with Non-Cannabis Additives" for an inhalable cannabinoid product that is a marijuana item; or¶

(B) "Inhalable Hemp Cannabinoid Product with Non-Cannabis Additives" for an inhalable cannabinoid product that is a hemp item.¶

(b) In the item's ingredients section of CTS, for all non-cannabis additives used in the item, with:¶

(A) ~~The name of the non-cannabis additive; and~~¶ Approved Label ID# for the product; and

(B) ~~The business name of the manufacturer of the non-cannabis additive.~~¶ The License # of the licensee who holds the label approval.

(2) ~~The ingredients recorded in CTS under (1)(b) of this rule must match the information that is contained in the header section of the non-cannabis additive's list of ingredients as required by OAR 845-025-3265(1)(a).~~ (This requirement becomes unnecessary).

Statutory/Other Authority: ORS 475B.025, 475B.070, 475B.090, 475B.100, 475B.560, 475B.105 Statutes/Other Implemented: ORS 475B.177

845-025-7120

The amendments to this rule describe how inhalable cannabinoid products that contain non-cannabis additives must list and label ingredients.

This section has similar but even more serious and likely problems as the previous section due to the requirement to list the ingredient manufacturer's name, in this case in tandem with the ingredients list for the additive in descending order of predominance. As mentioned previously, this does not seem necessary, will add to the overall de facto ban nature of the current draft, which the agency clearly knows based on testimony from the most recent RAC meeting. It also doesn't seem to have any functionality in terms of the fundamental goals of the rule and is clearly above and beyond the basic requirements of the Gov.'s recommendation.

Instead it seriously exposes both the licensee using the flavor ingredient and the manufacturer of it to unnecessary and significant damage to trade secrets and competitive advantage. Again, I'm wondering why this redundant listing of the manufacturer in these places has now been added to the rule language? All I can come up with is that it's another layer in discouraging ingredient manufacturers from selling into the Oregon market. Especially given that fact that no clear justification is documented here, as has been done for most other sections.

In this instance, with both ingredient list and manufacturer listed together, it can and will likely cause the following situations types of situations:

- In this case, any competitor of a successful brand can find out the flavor additive's supplier then go directly to the manufacturer of the key ingredient, i.e. the flavor, and "knock off" the product and cut into the initial brands success, without spending the investment the original brand had to put in to create the product and the demand for it.
- The ingredient manufacturer is also exposed to loss of competitive advantage and back engineering of their products. Any of their competitors can quickly assess who manufactures successful flavors, get the list of ingredients and go to work on recreating it, and they know which brands are interested the flavor and possible targets to market a very similar product at a lower price.

I'm curious to know how this functionally supports the fundamental goals of the rule and is rationalized as an appropriate and necessary requirement in fulfilling the Gov.'s recommendations? All I can come up with, as I have said repeatedly, that it has no real function other than to help disincentivize ingredient manufacturers from supplying the Oregon market.

In fact, an argument can clearly be made that it violates the "trade secret" protections per ORS 192.345, which is referenced in Section 7160. This reference indicates that the agency does understand and want to be sympathetic to trade secrets and their protection. The requirement that the ingredient manufacturer's name be on the labels and in CTS should absolutely be dropped.

The requirement to list all of an additive's ingredients in order of predominance in and of itself holds potential dangers, but combining it with the manufacturer's name is far more likely to create unnecessary damage to licensees and their suppliers.

CHANGES TO RULE:

845-025-7120
Cannabinoid Products Other than Cannabinoid Edibles, Topicals, Tinctures or Capsules.
(16) For inhalable cannabinoid products that contain non-cannabis additives:¶
(a) The product identity must clearly identify that the product contains non-cannabis additives and, in addition to the other requirements of OAR 845-025-7000 through 845-025-7190, must include the words "non-cannabis additive."¶
(b) In addition to the other ingredients in the inhalable cannabinoid product, for each non-cannabis additive used, at minimum the ingredient listing must contain the words "non-cannabis additive," and the name of the non-cannabis additive ~~and business name of the manufacturer of the non-cannabis additive~~ as contained in the list of ingredients required by OAR 845-025-3265(1).¶

a In the case where the non-cannabis additive is a flavor it can be:

i Listed as "non-cannabis natural and/or artificial flavoring, and (NOTE: This is actually a more accurate descriptor of the ingredient than "non-cannabis additive")

ii The name of the flavor must appear on the packaging. (Could even require it specifically on the Primary Display panel).

The reason for this change is the fact that most vape cartridge's packaging and labels are quite compact and "real estate" on them is very limited AND the name of the flavor is already very predominantly displayed on the packages primary display panel and therefore does not need to be redundantly added to the ingredient list thus saving valuable packaging/label "real estate". This also holds true for individually packaged enhance pre-rolls which use BDT's, which in many cases have even less space when a standard child proof tube is used for these products. The use of these tubes is very common

This suggested revision is basically the way these packaging and label requirements already are established, and they accomplish the same functions in terms of consumer awareness which is one of the fundamental goals of this rule.

The other great benefit is that it mitigates some of the need to revise and or redesign the packaging, saving cost and labor time for licensees. This hold true specifically if the full ingredients list is on an insert, wherein that may be the only modification to the packaging and therefore the current packaging does not need revision or full redesign.

(c) All of the ingredients in the non-cannabis additive:¶

Although this is not formally a requirement per the Gov.'s recommendation AND in fact, the only edit to the final draft of those recommendations was to make clear that the additives specific ingredients need *only be disclosed to the regulator*. This requirement should be removed as far as licensees who manufacture and sell these product, along with their

suppliers, are concerned for reasons listed below. Or, if left in, a web based option should be allowed along with the other options.

I will redline this language in a fashion that will be palatable enough to avoid the "de facto ban" effect.

(A) Must match the ingredients identified on the list of ingredients required by OAR 845-025-3265(1);¶
(B) ~~Must be listed in descending order of predominance by weight or volume; and~~¶ NOTE: Removal of this clause would allow manufacturer's and licensees the options to list in alphabetical order, which has been discussed and agreed upon by the stakeholders I've consulted with as a reasonable compromise.

Rational here: This requirement is unprecedented as far as I know in terms of how flavors are listed in any industry. In general practices based on CFR 21, the ingredients of flavors do not have to listed on consumer packaging due to a clear understanding and respect for flavor manufacturer's trade secrets. Therefore, some liberty with standard "order of predominance" requirements should be seriously considered as this may set a new precedent beyond the Oregon market. Given that this requirement is unprecedented, an unprecedented solution to how the information is listed which provides more protection for trade secrets, should be allowable and serious considered.

The "order of predominance" strategy definitely makes it far easier to back engineer a formula, whereas an alphabetical list makes it many orders of magnitude more difficult. If you going to require this level of exposure, i.e. unprecedented listing all the ingredients in the flavor, it seems more than reasonable that you have some consideration for allowing as high a level of trade secret protection as possible.

For consumers, the order of predominance strategy does very little in terms of their risk assessment of the product. These additives represent a minor % of the final products, and in fact many of the individual components end up in the product at far lower amounts than are allowed for toxic solvent residues. Without the consumer knowing the exact %'s of each specific ingredient, nor it's concentration in the final product, along with the fact that flavor formulations vary wildly from one to the next in the individual ingredient %'s (far more so than many analogous situations in other products like chocolate chips in a cookie product) …the main value of this list to the consumer, if they are interested enough to pay attention to this list, is just knowing in a general sense what's in there.

The alphabetical list does this as well as the order of predominance list, whereas the order of predominance list is more dangerous in terms of trade secret protection.

A few very reasonable and strong assumptions that also add weight to allowing the alphabetical option are as follows:

- A very high majority of consumers will likely look at this list once very briefly, if at all, and never again.
- Of those who pay attention to it, a very small percentage of them will go so far as to look up the 20-60 chemicals that are listed to make any kind of serious risk assessment.
- There is a much greater chance that the primary people who will want to get this list and pay close attention to it are the brand and flavor vendor's competitors, particularly the latter, so they can attempt to back engineer the product.

Personally, I'll be suggesting to my clients that they should include a clear indication of which of the ingredients are also found in cannabis, and which are not. Many flavor formulas will be predominantly compounds found in cannabis, this added nuance to the consumer listing will help overcome the unfair and negative consequences of some consumers being scared away from the products for the sole reason that a long list of chemical names can intimidate and spook people, in this case for no good reason. This sort of consumer would likely have a similar reaction if all the components of cannabis derived flavor extracts were exposed in a similar fashion. In this case, many compounds not originally found in the plant would likely be listed due to changes to the composition caused by the extractive process.

Believe me when I say, the people who rail against these products are very happy that they have finally gotten the agency to make this requirement and will also be some of the primary parties using this data to unfairly and maliciously cast

doubt on these products and the brands and processors involved. This already occurs without these lists available, i.e. the “fake terp” disparagements, and this will make it much worse. This is yet again going to cause further unnecessary, unfair negative impact to those businesses involved with these products…via a requirement that is not going to add significantly to protecting public health nor impact consumer risk assessment in a significant fashion, in my opinion.

(C) Must be listed on:¶
(i) The label's ingredient list as sub-ingredients of the ingredient term "non-cannabis additive"; or¶
(ii) An insert within the product's package that clearly indicates that the ingredients listed are contained within the inhalable cannabinoid product.
(iii) An accordion style label.

This added option is already available for many labeling applications and should be extended to this “new” classification.

I would also argue that a QR code web based option be seriously considered, if not in this initial additives rule then in the future. The vast majority of people who may be interested in reviewing this information do have digital access of one form or another.

Statutory/Other Authority: ORS 475B.605, 475B.232, 475B.236 Statutes/Other
Implemented: ORS 475B.605

845-025-7160

These rule changes require inhalable cannabinoid products that contain non-cannabis additives to have pre-approved labels compliant with these rules prior to being sold to consumers.

A big issue in this section is the idea that in general the flavor ingredient manufacturers do not want to turn over their ingredient decks with %’s to licensees. Even with an NDA in place they rarely do this, for obvious reasons discussed in earlier comments.

The agency can fulfill its need to get this information and associate it with the proper product and label, with the information coming directly from the manufacturer who will be cued to do so by the licensee who wants to use the ingredient and is applying for labels to market the final product.

The other big advantage of these suggestions is that the agency can be assured the information coming directly from the ingredient manufacture is accurate and has not been edited by licensees. This will also insure that the manufacturers are fully aware that they are providing information and product specifically for inhalable products. It’s not likely that Schillings, a vanilla flavor manufacturer for food use, will comply with these requirements, thus inappropriate off the shelf food or fragrance products will not enter the supply chain.

In a nut shell, manufacturers who make products for these purposes retain a reasonable level of trade secret protection and the agency and industry have a tool to keep inappropriate products out of the market.

The redlines below accomplish this.

CHANGES TO RULE:

845-025-7160
Packaging and Labeling Pre-approval Process

(~~3~~C) For label applications for inhalable cannabinoid products that contain non-cannabis additives:¶

(i) The non-cannabis additive's list of ingredients ~~as required by 845-025-3265(1)~~ with each ingredient's range of concentration. This list may be supplied directly by the additive manufacture, and if it is, must clearly reference in its header both the licensee's license number AND the label application ID# for which it is being submitted; and¶

This revision takes care of the problems discussed previously and allows the licensee and their supplier the ability to make the "business-to-business" decision as to whether the licensee should get the full recipe on a case by case basis, depending on contractual arrangements and the comfort level of the manufacturer in terms of disclosing this much information (even under NDA).

The agency still gets what it needs, in a fashion that will be easy to add the ingredients list to the appropriate label application, and allows maximum flexibility on this very sensitive issue between the licensee and the additive manufacturer…and as mentioned above furthers the ability to keep inappropriate products out of the supply chain.

(ii) In a form and manner prescribed by the Commission, information regarding the manufacturer of the non-cannabis additive, the additive or additives being used by the licensee, and attestation by the licensee of the accuracy of the information submitted for label pre-approval.¶

(3) If a licensee submits a list of ingredients to the Commission in order to comply with (2)(b)(C) of these rules, and that the licensee believes the list of ingredients is a trade secret, the licensee must mark the information "confidential - trade secret."¶

(a) If the Commission receives a public records request for information submitted by a licensee, it will review all documents submitted to determine whether the documents contain trade secrets that would be exempt from disclosure under Oregon's Public Records Act, ORS 192.345.¶

(b) For purposes of this rule "trade secret" has the meaning given that term in ORS 192.345.¶

845-025-7190

These rules require inhalable cannabinoid products manufactured on or after February 1, 2021, and that contain non-cannabis additives to have pre-approved labels compliant with these rules prior to being sold to consumers. For inhalable cannabinoid products that contain non-cannabis additives and that are manufactured prior to February 1, 2021, licensees have until July 1, 2021 to do the following: sell the items in inventory, bring any remaining inhalable cannabinoid products with non-cannabis additives into compliance with revised and pre-approved labels, and/or destroy the items.

For reasons state above:

CHANGES TO RULE:

845-025-7190
Effective Date

(1) For inhalable cannabinoid products that contain a non-cannabis additive and are processed or manufactured on or after ~~February~~ May 1, all labels must be pre-approved by the Commission in accordance with these rules.¶ (a) An inhalable cannabinoid product with a label approved by the Commission prior to February 1, 2021; that contains a non-cannabis additive; and that does not meet the requirements of OAR 845-25-3265 or 845-0257120 may not be possessed, sold, delivered, transferred, transported, purchased, or received on or after ~~July~~ October 1, 2021.¶

(b) An inhalable cannabinoid product that contains a non-cannabis additive; that is manufactured prior to ~~February~~ May 1, 2021; and that has a compliant generic label may be possessed, sold, delivered, transferred, transported, purchased, or received prior to ~~July~~ October 1, 2021.

Statutory/Other Authority: 475B.236, 475B.620, ORS 475B.605, ORS 475B.615 Statutes/Other Implemented: ORS 475B.605

AMEND: 845-025-8520

RULE SUMMARY: Amendments to this rule apply the prohibition to possess, sell, deliver, transfer, transport, purchase, or receive an inhalable cannabinoid product that does not comply with OAR 845-025-3265 on or after July 1, 2021, to all license types. For inhalable cannabinoid products that contain non-cannabis additives and that are manufactured prior to February 1, 2021, licensees have until July 1, 2021 to do the following: sell the items in inventory, bring any remaining inhalable cannabinoid products with non-cannabis additives into compliance with revised and pre-approved labels, and/or destroy the items.

CHANGES TO RULE:

845-025-8520
Prohibited Conduct ¶

Prohibited inhalable cannabinoid products.¶

(a) For purposes of this rule, a "prohibited inhalable cannabinoid product" is an inhalable cannabinoid product that does not meet the requirements of OAR 845-025-3265 and 845-025-7160¶

(b) No licensee or permittee may:¶

(A) Process or manufacture a prohibited inhalable cannabinoid product on or after ~~February~~ May 1, 2021; ¶

(B) Possess, sell, deliver, transfer, transport, purchase, or receive the prohibited inhalable cannabinoid product on or after ~~July~~ October 1, 2021, if the prohibited inhalable cannabinoid product was processed or manufactured prior to ~~February~~ May 1, 2021; or¶

(C) Possess, sell, deliver, transfer, transport, purchase, or receive a prohibited inhalable cannabinoid product that was processed or manufactured on or after ~~February~~ May 1, 2021.¶

(c) An intentional violation of this section is a Category II violation.¶

(d) An unintentional violation of this section is a Category III violation.¶

From: Joe Bergen
To: OLCC.Rulemaking * OLCC
Subject: Additives Rules Comment
Date: Monday, November 23, 2020 2:05:53 PM

To whom it may concern:

My name is Joe Bergen. I am the General Manager of a licensee that manufactures several vape brands here in Oregon. I am writing in opposition to the proposed amendments for inhalable additives in Chapter 845.

I'd like to start by congratulating the commission with a successful conversion of an illegal production economy and a loosely regulated medical market to a well-regulated legal market. By converting the illicit market which was fraught with exploitation, high concentrations of pesticides and dangerous materials in products, and sometimes violence to a legal one that has produced positive outcomes, in the Oregon economy, product safety, and access to cannabis by underage users.

We believe that the rule-making process failed to incorporate consumer demand, failed to utilize a sound body of evidence, and filed to include the input of cannabis business.

As a company, we support a comprehensive plan to protect consumer safety, consumer choice, promote sustainable businesses and a thriving marketplace in Oregon. We envision a regulated market where consumers are provided with accurate information aimed at product safety and consumer protection. We respectfully disagree with the proposed rule changes on the following grounds:

1. The OLCC has provided no evidence that at least two of the additives listed in the ban are or were the cause of Vape Associated Lung Injury. Products using additives containing MCT and PG are and will continue to be used in other non-cannabis vape products and sold at non-cannabis vape shops and convenience stores in Oregon. We believe that substantives science-based evidence must be provided by the commission in the event that additives are banned. In our opinion it is poor practice to isolate a segment of the cannabis industry in banning substances without evidence that there are threats to public health or consumer safety.
2. The rulemaking process has failed to seek consumer input on the impact of the ban. The existing ban will eliminate 6 of the top 10 best-selling vape cartridges in OR according to Headset Data which is a leading cannabis market and analytics provider. Consumers clearly want a wide array of choices for vape cartridges and the OLCC should seek consumer input before implementing dramatic changes to the rules.
3. The OLCC suggests that 5-10% of products will be impacted by this rule, and the data that we see suggests that more than 25% of products actually sold in Oregon over

the past year could be impacted by the ban. The OLCC should be required to utilize the data in CTS to develop a more comprehensive analysis of the economic impact to our state.

4. The proposed rules will require manufacturers to disclose all ingredients of their additives and state that their products are "intended for inhalation." Many of the existing additives manufacturers have thus far stated that the rules are onerous and require disclosures that threaten their Intellectual Property and their business and as a result will choose to no longer do business in Oregon.

5. Lastly, speaking directly to the impacts of our company, the rules will result in significant loss of revenue and a reduction of our existing staff by up to 40%, and a dramatic reduction from our suppliers of cannabis extract and trim. We estimate this will have a much broader impact than is described in the economic impact statement and more due diligence must be done.

In short, we believe that the proposed rules create a de-facto ban on vape products containing additives, limit choices for consumers many of whom favor products with additives in them, create restrictions in the market without evidence or rationale for the banning of certain additives, and require the disclosure of Intellectual Property which is uncharacteristic of any other cannabis market in the country. The OLCC should strongly consider engaging the cannabis industry in the development of regulations that will provide protections for consumer safety, consumer choice, and only ban additives that are backed by a reasonable threshold of evidence shown to pose a threat to consumer health.

Sincerely,
Joe Bergen

Joe Bergen
General Manager
AVITAS OREGON CANNABIS
e: joe@avitasag.com
p: 503-750-2266
www.avitasgrown.com

From: Cecilia Garcia
To: OLCC.Rulemaking * OLCC
Subject: Ammendments Re: Vape products in Chapter 845
Date: Sunday, November 22, 2020 2:03:58 PM

I work for a company that is licensed by the OLCC recreational marijuana program and manufactures several vape brands here in Oregon. I am writing in opposition to the proposed amendments to new regulations for vape products in Chapter 845.

The proposed rules will result in regulations that will ban nearly 40% of the products that we manufacture and thereby puts the jobs of many of my co-workers in jeopardy. The rationale for the change in rules does not appear to be consumer driven, endorsed by the industry at large, nor backed up by compelling evidence for product safety. As a result, I respectfully request that you strongly consider redeveloping the rules to be aligned with consumer demand, utilize sound evidence based in science in determining which additives to ban, and not overly onerous to compliant businesses that are operating in good faith in the Oregon cannabis market.

In short, the proposed amendments to marijuana additives will limit consumer choices and result in the destruction of cannabis jobs. The OLCC should strongly consider engaging the cannabis industry in the development of rules that will provide protections for consumer safety, consumer choice, and only ban additives that are backed by a reasonable threshold of evidence shown to pose a threat to consumer health.

Sincerely,

Cecilia Garcia

From:	eos labs
To:	OLCC.Rulemaking * OLCC
Subject:	Comment on OLCC Notice of Proposed Rulemaking - Inhalable Cannabinoid Product Additives
Date:	Sunday, November 15, 2020 10:55:09 PM

To Whom It May Concern,

As an OLCC licensed processor I would like to address two points within the proposed rule 845-025-3265. First, the rule under section (2)(e) specifically prohibits the use of Propylene Glycol. The Food and Drug Administration (FDA) maintains an inactive ingredient database listing all ingredients and approved routes of administration. As one can see, the FDA has specifically approved Propylene Glycol as an inactive ingredient for inhalation route. The proposed OLCC rule is in disagreement with the FDA in this regard, and several FDA approved inhaled medications containing propylene glycol have been available in the pharmaceutical market for many years. The caveat is that the inhalation route to the FDA means delivery through a metered dose inhaler or a nebulizer as these are the only FDA approved inhalation devices. There are no FDA-approved vaporizers so it would not apply to these devices. I mention this because while we applaud the OLCC's effort to address the vaporizer safety concerns, our second point to address is the language is overly broad and covers "all inhalation products." Our company makes a metered dose inhaler which would fall under this language despite being mechanistically different from vaporizers, not posing the same safety concerns, having adequate evidence over years of inhaler technology to demonstrate safety, and not applying heat as vaporizers do which introduces the possibility of chemical conversion of ingredients.

The OLCC's Notice of Proposed Rulemaking document under the section "Need for the rules" 845-025-3265 discussing vaping associated lung injury states "Research has shown that certain substances, when heated under common cannabis vaping conditions and inhaled into the lungs can have serious negative health consequences."
Clearly vaping injury is the concern being addressed in these rules, so we feel that the rules should specifically state "vaporizer products" and that general language for all inhalation products, particularly those that don't employ heat, is unnecessarily broad and negatively impacts safer inhalation modalities. Second, propylene glycol is an FDA approved inactive ingredient in inhalers and nebulizers where no heat is applied. This ingredient should be allowed in non-vaping inhalation devices.
Thank you for your consideration.

Greg Roberti
Eos Labs

Reference

FDA Approved Inactive Ingredient Database (includes inhaled routes for ingredients used). https://www.accessdata.fda.gov/scripts/cder/iig/index.Cfm.

From: m lindgren
To: OLCC.Rulemaking * OLCC
Subject: Proposed vape ban
Date: Monday, November 23, 2020 8:31:55 AM

I work for a company that is licensed by the OLCC recreational marijuana program and manufactures several vape brands here in Oregon and am directly involved in manufacturing the product. I am writing in opposition to the proposed amendments new regulations for vape products in Chapter 845.

The proposed rules will result in regulations that will ban nearly 40% of the products that we manufacture and thereby puts the jobs of many of my co-workers in jeopardy. The rationale for the change in rules does not appear to be consumer driven, endorsed by the industry at large, nor backed up by compelling evidence for product safety. As a result, I respectfully request that you strongly consider redeveloping the rules to be aligned with consumer demand, utilize sound evidence based in science in determining which additives to ban, and not overly onerous to compliant businesses that are operating in good faith in the Oregon cannabis market.

In short, the proposed amendments to marijuana additives will limit consumer choices and result in the destruction of cannabis jobs. The OLCC should strongly consider engaging the cannabis industry in the development of rules that will provide protections for consumer safety, consumer choice, and only ban additives that are backed by a reasonable threshold of evidence shown to pose a threat to consumer health.

Sincerely,
Merlynn Lindgren
mlindgren9@gmail.com
541-220-5004

From: Bobbi Jacobson
To: OLCC.Rulemaking * OLCC
Subject: proposed vape regulations
Date: Monday, November 23, 2020 3:03:53 PM

Good afternoon,

I am a consumer of vape products licensed by the OLCC recreational marijuana program and I am writing in opposition to the proposed amendments and/or new regulations for vape products in Chapter 845.

The proposed rules will ban flavored vape cartridges which contain a small amount of MCT oil in them. As a consumer, I enjoy the ability to make my own decisions about the products I consume and do not understand why the OLCC is taking such a dramatic step to ban PG and MCT in all regulated cannabis vape products. Other non-cannabis vape products (such as nicotine vapes) contain much higher amounts of PG and MCT than cannabis vape products and will still be sold in vape shops and convenience stores, yet cannabis products with much lower amounts of PG or MCT will be banned. Surely you can see how this is not logical.

As a consumer I want access to a variety of flavored vapes. I suggest that we have regulations that offer a wide array of products for consumers and let us decide which products we want to buy.

Sincerely,

Bobbi Jacobson
Operations/Brand Manager
406.250.2172

leaflink.com/pharmers-market
pharmersmarketor.com

From:	Matt Leiphart
To:	OLCC.Rulemaking * OLCC
Cc:	Eric Huynh; Erik Stewart
Subject:	Public Comment on Added Substances in Marijuana - Rules Package (Chapter 845 filed 10/30/20 4:04pm)
Date:	Friday, November 13, 2020 9:00:06 AM
Attachments:	OLCC-Public-Hearing-Notice-Marijuana-Additives-Package.pdf

Greetings OLCC - Please accept the following public comments for consideration of proposed rules package for added substances in marijuana. The notice of proposed rulemaking is attached for reference. Where comments pertain to specific text in the rules package, that text is quoted in the comments below.

****

OLCC Section - Need for the Rule(s)
OLCC states, "These rules are intended to reinforce the Oregon Liquor Control Commission's ability to protect public health and safety, by specifying the standards for non-cannabis additives being used in inhalable cannabinoid products related to disclosure of ingredients and declarations of intended use."

Public Comment - OLCC requires testing to detect known dangerous contaminants (residual solvents and pesticides). Current testing requirements and identification of ingredients by CAS number provides positive identification of the constituent components of each additive. Appropriate protection of consumer safety is afforded by ingredients disclosure and testing for dangerous contaminants. Requiring a statement of intended use provides no safeguards for consumers and does nothing to protect public health and safety.

****

OLCC Section - Need for the Rule(s) - 845-025-3265
OLCC states, "The precise causative agent of EVALI is still unknown and may never be known due to the many variables and complex chemistry that occurs in vaping products."

Public Comment - Extensive evaluation and testing of substances from known EVALI cases implicated vitamin E acetate, marijuana concentrate from black market sources containing known dangerous contaminants, and use of black market vape cartridges containing known dangerous contaminants. Testing for vitamin E acetate and other known contaminants within a market environment where the black market does not thrive is the intelligent approach to take. Banning BDTs with onerous, ineffective bureaucratic hoops designed to encourage legal licensees to take products with BDTs off the market encourages black market actors to fill demand for these products. Instead of an approach that detects dangerous products and protects consumers via enforcement, these steps provide a doorway for increasing penetration into the Oregon market by the dominant US black market sources present in California. (See https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html supporting assertions that nothing in BDTs caused EVALI illnesses and deaths.)

****

OLCC Section - Cost of Compliance
OLCC states, "The onset of the rule is February 1, 2021, and the sell-down period for previously approved inhalable cannabinoid products with non-cannabis additives is a further six months. The OLCC estimates that this amount of time will be sufficient for licensees to redesign labels and order/design new packaging."

Public Comment - The February 1, 2021 introduction date is too soon to feasibly attain. Not only must labels be designed, and ingredient submissions made, but OLCC approval is required on labels. Our organization's experience obtaining label approval from OLCC indicates current lead times are 30+ days from submission of label for approval to receipt of approval from OLCC. If rules went into effect on December 1, 2020, and labels from all affected parties were submitted to OLCC on December 1, and assuming OLCC could provide approval for all labels by January 1 (30 days after submittal), that allows only 31 days to order and receive new labels for use in marijuana product manufacturing activities. If laboratory analysis requirements will be implemented to support ingredients declarations, this lead time cannot be accommodated by the February 1, 2021 introduction date. Even in this best case scenario (all labels submitted on December 1, supported by documented laboratory results if required) it will be impossible to provide compliant product by February 1, 2021.

OLCC states, "Revisions of new labels and (optional) label inserts to meet ingredient disclosure requirements would also be required, although OLCC estimates that only minor revisions would be required."

Public Comment - Adding a list of ingredients by CAS number, including identification of manufacturer for each ingredient is a significant change (not minor) and will add cost, either through using an accordion label (if authorized) or adding an insert as presented by OLCC. Will accordion style labels or an equivalent be acceptable to allow the long lists of ingredients on labels?

****

CHANGES TO RULE: 845-025-7120
Revised Requirement, "(16) For inhalable cannabinoid products that contain non-cannabis additives:...
(c) All of the ingredients in the non-cannabis additive:...
(C) Must be listed on:...
(i) The label's ingredient list as sub-ingredients of the ingredient term "non-cannabis additive"; or
(ii) An insert within the product's package that clearly indicates that the ingredients listed are contained within the
inhalable cannabinoid product.

Public Comment - An insert is listed as acceptable to meet ingredients requirements. What information must be displayed on the outside of the container, and what information is allowed to be present on an insert which is not visible to a customer prior to sale? Will accordion style labels or an equivalent be acceptable to allow the long lists of ingredients on labels?

****

CHANGES TO RULE : 845-025-3265
Revised Requirement, "(1) A processor may only use a non-cannabis additive in an inhalable cannabinoid product if the non-cannabis additive is accompanied by a list of ingredients from the manufacturer of the non-cannabis additive that:
(a) In a header section, displays the name of the non-cannabis additive and the business name of the manufacturer of the non-cannabis additive;
(b) In clear and legible font, includes a statement that each of the ingredients in the non-cannabis additive is for use in a product intended for human inhalation;

(c) Accurately identifies all ingredients in the non-cannabis additive; and
(d) For each ingredient of the non-cannabis additive, includes:
(A) A Chemical Abstracts Service Reference Number that specifies the ingredient's isomer and, if applicable, enantiomer; and
(B) The ingredient's maximum concentration within the non-cannabis additive."

Public Comment - Must ingredients disclosures be supported by test results identifying each component, or will declarations of ingredients from manufacturers be sufficient? If test results from OLCC labs are required, what consideration has been given to the capacity of OLCC approved labs for performing the necessary analysis and testing? Do OLCC labs have the capacity to process testing requests in a timely manner that will support the stated introduction date of February 1, 2021?

****
CHANGES TO RULE: 845-025-7160
Revised Requirement, "(3) If a licensee submits a list of ingredients to the Commission in order to comply with (2)(b)(C) of these rules, and that the licensee believes the list of ingredients is a trade secret, the licensee must mark the information "confidential - trade secret."

Public Comment - Provisions are present in the rules for identification of "confidential - trade secret" ingredients when applying for label approval. Requirements for disclosure of ingredients and ingredient manufacturer on labels eliminates trade secret protections. Why allow trade secret identification for submittals to OLCC when protections are eliminated via requirements for disclosure on labels?

****
CHANGES TO RULE: 845-025-3270
OLCC States, (in Rule Summary), "...the rule requires that licensees record the additive name(s) and manufacturer(s) in these items in a way that matches the information on the additive's required list of ingredients. These two requirements will provide the OLCC with greater line of sight to which specific non-cannabis additives are on the market and in which items."

Public Comment - Disclosing additive ingredients and manufacturers in CTS will provide a line of sight for unscrupulous operators to reverse engineer additives, eliminating competitive advantage of legitimate manufacturers, and providing the opportunity for black market operators to introduce exact duplicates of compliant product without the protections of these same rules which are being promulgated. If implemented as documented, this rule affords a straightforward means of placing black market product on the market, circumventing OLCC's control and protection of consumer health and safety.

Ingredients disclosures to the level suggested will provide information required of the black market to replicate successful brand formulations, and provide cheaper products that are more accessible (given the nature of black market operations) without testing to ensure safety. The keys to the vape market will be handed to black market operators - increasing accessibility to information needed to copy proven brands, while decreasing accessibility to products from licensed producers via additional costs, long lead times for approval from OLCC, and shortages of viable ingredients as BDT manufacturers exit the Oregon market.

****
CHANGES TO RULE: 845-025-3270
Revised Requirement, "(1) On and after February 1, 2021, any inhalable cannabinoid product possessed by a licensee, research certificate holder, or hemp certificate holder that contains a non-cannabis additive must be recorded in CTS:
(a) With the item category of:
(A) "Inhalable Cannabinoid Product with Non-Cannabis Additives" for an inhalable cannabinoid product that is a marijuana item; or
(B) "Inhalable Hemp Cannabinoid Product with Non-Cannabis Additives" for an inhalable cannabinoid product that is a hemp item.
(b) In the item's ingredients section of CTS, for all non-cannabis additives used in the item, with:
(A) The name of the non-cannabis additive; and
(B) The business name of the manufacturer of the non-cannabis additive.
(2) The ingredients recorded in CTS under (1)(b) of this rule must match the information that is contained in the header section of the non-cannabis additive's list of ingredients as required by OAR 845-025-3265(1)(a)."

Public Comment - Disclosure of ingredients and manufacturers to OLCC is required in revised rule 845-025-3265. If OLCC would implement a means of identifying approved additives through unique OLCC-assigned additive identification, this would allow notification to consumers that inhalable cannabinoid products contain approved ingredients without disclosing detailed information which may be used to eliminate the competitive advantage of manufacturers and brands. If this approach were used, the names of non-cannabis additives and manufacturers could be replaced with an OLCC identifier.

We are grateful for the opportunity to provide feedback on the new proposed rules for added substances in marijuana. If you have any questions or require additional action on our part, please let me know.

Sincerely,

--

Matt Leiphart
Senior Director of Quality

Phone 720.454.6904
Email matt.leiphart@airobrands.com
Website www.airobrands.com

From:	Laura Probst
To:	OLCC.Rulemaking * OLCC; Kane Madeline * OLCC
Cc:	Dustin Jessup; Colby Huling
Subject:	Public Comment re: 2020 Added Substances in Marijuana Rules Package
Date:	Monday, November 23, 2020 4:50:06 PM
Attachments:	image002.jpg image004.jpg Herban_Industries_Public_Comment_on_Proposed_Rules_11_23_20.docx

Thank you for the opportunity to participate in the public comment process and submit input on behalf of our company, Herban Industries OR, LLC (dba Winberry Farms/DYME Distribution), which has been part of Oregon's regulated adult use cannabis market since 2016. If passed as is, the proposed rules could negatively impact several of our primary product lines, comprising at least 30 SKUs and a large percentage of our annual revenue.

While we understand the objectives of the proposed rules are to enhance transparency for consumers and protect public health/safety, the current language is not grounded in science and overreaches the intent of the recommendations put forth by the Governor's Vaping Task Force. Our company has numerous concerns with the draft language as it stands and encourages the OLCC to consider other options for achieving the rule's goals in order to reduce negative economic impact on not just small, but all businesses operating within Oregon's cannabis industry.

Our primary fear is that OLCC's proposed rules as currently written with the "intended use" statement will create a de-facto ban on all inhalable cannabinoid products that use non-cannabis additives, subsequently resulting in the loss of jobs and revenue, which is bound to devastate – if not completely shut down - small cannabis companies across Oregon (an estimated 657 of them according to page 8). Even if the rules are modified to avoid this scenario, there are several other components that will have a significant adverse fiscal impact on our industry. Given the state's economy is already suffering due to COVID restrictions, it seems that now is not the time to scrutinize a system that has been working for the past 3+ years.

We are in favor of further regulations and protections, including prohibiting certain additives/ingredients based on science, and creating more stringent disclosure/labeling requirements for inhalable cannabinoid products, but think this can be achieved through other strategic processes that better align with the current regulations that small, established cannabis businesses have been accustomed to.

Below are some key points we think would provide a more reasonable approach to this process and help reduce the economic impact of the rule on small businesses. It is our hope that the Agency will work through the proposed pathways more before implementing them.

INTELLECTUAL PROPERTY PROTECTION & REGULATION OF TERPENE MANUFACTURERS

- We recommend the Agency do further due diligence with terpene/flavor ingredient manufacturers to determine a feasible pathway to its intended goal, such as creating regulations/standards within this market segment.
- Many of these companies may not be able and/or willing to meet the current onerous requirements due to concerns over Intellectual Property and potential loss of product liability

insurance, among other issues, which would likely result in them ceasing to do business in Oregon.

- Should the rules language get approved and businesses are able to comply, their product "recipes" should only be provided to the OLCC under a non-disclosure agreement and not shared broadly with the general public as the specific ingredients and amounts used are intellectual property (IP) for small businesses.
- If botanically-derived terpenes are a key concern, the OLCC should work with industry partners to develop a regulatory framework for confirming manufacturers/suppliers meet certain safety criteria.
- Herban Industries OR, LLC recommends a less-stringent ingredient verification process that meets the directives in the Governor's recommendations, while allowing operations to continue for established cannabis companies that do not have reported and validated proof of their products causing adverse effects/human harm.
- As part of a one-time due diligence process, processors could register their ingredients with the OLCC under an NDA and get placed on an approved vendors list.
- Whatever process is adopted should conform with information currently available via Safety Data Sheets rather than mandating new requirements that may not be feasible to attain.

TIMELINE

- Should the proposed rules get pushed through as is, the sell down periods set for February 1, 2021 and July 1, 2021 are unrealistic. The agency should consider adjusting its timetables for implementation of the proposed rules.
  - We recommend the sell down timetables not be established until further research can be conducted by labs and/or terpene suppliers to determine the processes, costs and timelines associated with all new testing criteria and product certifications that would be required by the proposed rules.
  - Alternatively, we recommend extending the onset and sell through dates by several months to allow more time for companies able to comply with the new regulations to navigate challenges with their manufacturers, packaging partners and others. For example, the rules could change to a July 1, 2021 deadline and a December 1, 2021 deadline.
  - Providing adequate lead times is critical given many businesses conduct planning and/or order packaging several months in advance of when it hits shelves.
  - Additionally, retailers need to participate in the sell down period and the agency needs to make it easy for them to do so and properly communicate to them regarding their importance in doing so. As we learned from the October 2019 moratorium on vape products with botanically derived ingredients, many retailers made the decision to stop selling and/or carrying these products well before the deadlines.

PACKAGING

- In the event that Herban Industries were able to find a compliant replacement for our current flavor ingredients and keep the doors open, the cost of redesigning packaging for all affected SKUs and the loss in revenue during that redesign period would result in well over $400,000.
  - The agency should not require that all detailed ingredients be printed on the label. If

companies are required to disclose all ingredients, the OLCC should allow this information to be communicated via a website.

CONSISTENT STANDARDS

- If this becomes a requirement for botanical vape products, then it should also be required for all smokable and inhalable marijuana products. If this standard is only applied to botanical vapes, consumers may falsely assume that other cannabis vapes are safe, although there is no current science to support either.
    - It would be best if the agency required all manufacturers, producers and/or retailers to include a simple warning label on all Inhalable Marijuana Products that conveys "Smoking or vaping may be harmful to your health. This product contains ingredients that have not been evaluated or approved for inhalation by the FDA, OLCC or other regulatory agency."
    - The OLCC should also consider creating a list of specific prohibited ingredients known to be harmful rather than a list of ingredients that are NOT known to be harmful and the policy should be guided by science.

Laura Probst
Marketing Manager
DYME Distribution | dymedistro.com
T | +1.503.830.4098
E | laura.probst@dymedistro.com

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From:	Jesse Sweet
To:	OLCC.Rulemaking * OLCC; Kane Madeline * OLCC
Cc:	Compliance
Subject:	Public Comments
Date:	Wednesday, November 18, 2020 1:34:25 PM
Attachments:	image003.png Groundworks November 2020 Rule Comments.pdf

---

Madeline:

I've attached my public comments on the October 30 rule package. I hope you're doing well and have a great holiday next week.

Best,
Jesse

Jesse Sweet
Director of Licensing & Compliance
Groundworks Industries

GW

INDUSTRIES

November 20, 2020

Oregon Liquor Control Commission
9079 SE McLoughlin Boulevard
Portland, OR 97222

RE: Public comments on proposed rulemaking to prohibit certain additives and create additional ingredient disclosure and labeling requirements for inhalable products. (October 30, 2020 Rule Package)

Dear Commissioners:

Please accept the following as Groundworks Industries' public comments on the proposed rules in the October 30, 2020 Rule Package. Groundworks Industries is a vertically integrated cannabis company with state-of-the-art production and processing facilities, wholesale distribution and retail channels. We currently hold 25 retail cannabis licenses.

Groundworks Industries supports the proposed changes to administrative rule. We are especially supportive of the requirements to add transparency and disclosure to the supply chain for inhalable products. In September 2019, Groundworks voluntarily removed all inhalable products containing non-cannabis ingredients from our retail shelves. We have no plans to stock these products again until definitive research is available to demonstrate their safety for inhalation. For those retailers and consumers who chose to sell and use these products, full ingredient disclosure is essential to making informed choices. Disclosure of ingredients should not be limited to general descriptions of additives. Instead, every individual component should be identified and should be accompanied by a statement that the ingredient is intended for inhalation. Such disclosure not only allows consumers to make informed choices in the present, but it also allows for swift correction should research identify additional compounds that are unsafe for inhalation.

224 SW 1ST AVENUE
PORTLAND, OREGON
97204

971.254.4290
GW-IND.COM
GROUNDWORKS INDUSTRIES

Thank you for considering my comments.

Respectfully,

Jesse Sweet
Director of Licensing and Compliance
Groundworks Industries

GW INDUSTRIES

From:	Rob O"Brien
To:	OLCC.Rulemaking * OLCC
Subject:	public consultation submission 845-025-3265 Inhalable Cannabinoid Product Processor Requirements
Date:	Sunday, November 22, 2020 9:55:34 AM
Attachments:	845-025-3256 Information submission Oregon.pdf 10-11-20 Report VP and ERSA.pdf

---

I have attached a letter and a report as a contribution to the public consultation process relating to rules associated with production of vaping products.

Thank you for the opportunity.

R.O'B

--
Rob O'Brien
CEO and CSO, Supra Research and Development
#106 - 2293 Leckie Road, Kelowna, BC, V1X 6Y5
r.ob@suprarnd.ca (250) 878-4711 http://www.SupraRnD.ca

Follow Supra R&D on Linkedin: http://www.linkedin.com/company/2929041
Rob's Linkedin profile: https://www.linkedin.com/in/suprarob

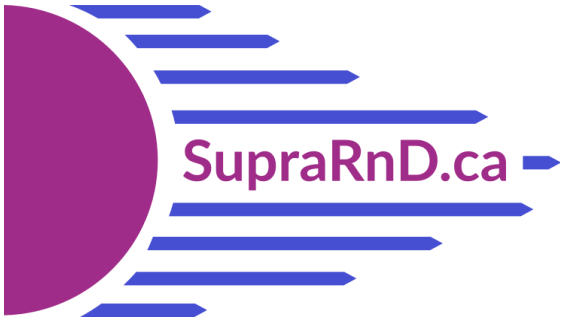
Vaporization Potential and

Effective Residual Solvent Analysis Report

Vitamin E Acetate, Squalane and Squalene

November 10, 2020

Prepared by



Supra Research and Development

Supra Research and Development Inc.
106-2293 Leckie Rd, Kelowna B.C. V1X 6Y5
http://suprarnd.ca/ | inquire@suprarnd.ca | 1-855-437-8772

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Supra Research and Development Inc.
106-2293 Leckie Rd, Kelowna B.C. V1X 6Y5
http://suprarnd.ca/ | inquire@suprarnd.ca | 1-855-437-8772

1.0 Introduction

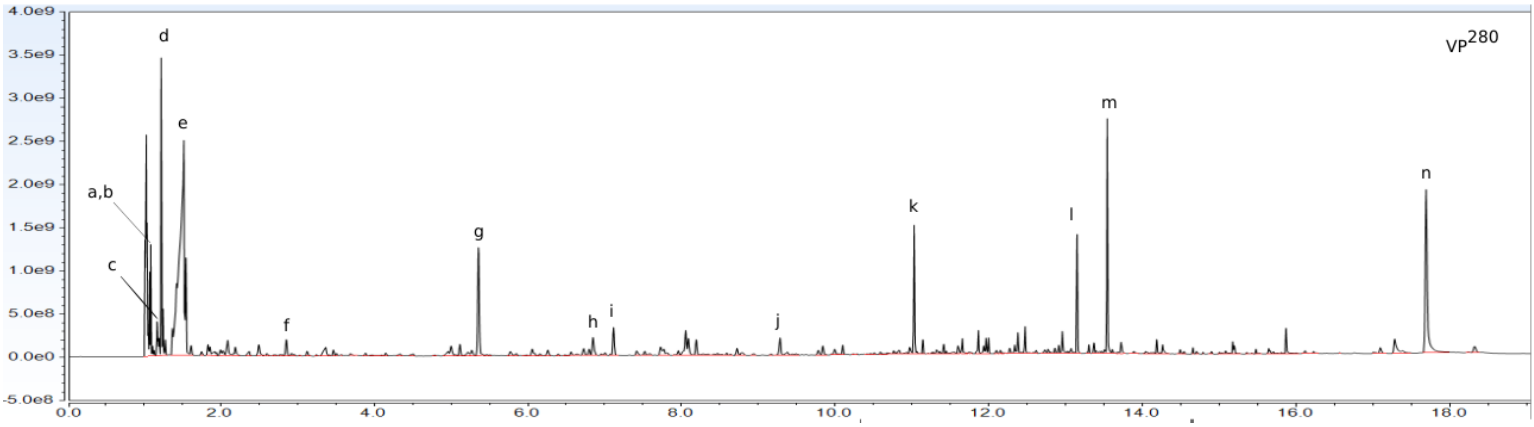
Consumer products that are intended to be consumed by inhalation after high temperature vaporization are a relatively new category of products that require a unique approach to determine the relative risks associated with consumer use. The most significant variable is that at elevated temperatures ingredients can rearrange, react and/or thermally degrade to create new chemical structures that can have fundamentally different chemical properties with different pharmacological consequences of use. This chemical change is dependent not only on the vaporization temperature but also on the composition of the material being vaporized. In some cases, compounds such as Vitamin E acetate which are Generally Regarded as Safe (“**GRAS”**) when introduced to a consumer at room temperature by ingestion may decompose to produce a complex mixture of chemical agents with significant toxicities at high temperatures. Furthermore, the lack of standardization for devices used to generate vapors after high temperature vaporization means that the temperature used is often unknown. Some of the compounds generated at elevated temperatures are themselves reactive and can further react, rearrange or decompose to alternate structures. This type of possible chemical behavior greatly complicated traditional chemical analysis as quantitation standards would also decompose at the temperatures in question. The sampling of vapors produced by devices is a potential approach to determine exposure risk for consumers of devices, however, the diversity of devices used makes determination of the correct devices to use for such studies a significant challenge. Regardless of the challenges, it is critically important to develop approaches to evaluate ingredients that could be used in products that are intended to be consumed by Inhalation after high temperature vaporization so that those materials that have a high likelihood of exposing the consumer to dangerous chemical agents are not used as ingredients. This work will highlight such an approach and apply it to the examination of 3 different potential ingredients, Vitamin E Acetate, Squalane and Squalene.

2.0 Vaporization Potential

Supra Research and Development (“**SUPRA**”) has developed an approach to determine the profile of the diverse range of thermally generated compounds generated by ingredients that are intended to be used in vaporizers. Rather than try and develop a standardized device for producing vapors, we use an analytical instrument that can heat a sample in a controlled manner and then collect and analyse the byproducts. The instrumentation we are using is called Headspace - Gas Chromatography Mass Spectrometry. In this approach a small quantity of sample is accurately heated in hermetically sealed glass vials to a series of well defined temperatures. At each temperature, a sample of the gas phase vapour, also called the “HeadSpace”, is collected and analysed. This analysis involves separation of individual chemical components in a Gas Chromatograph followed by detection in a Mass Spectrometer. The Mass Spectrometer allows for both identification of individual components as well as relative quantitation. The

information can be graphically displayed as a chromatogram where individual compounds are displayed as 'peaks'. A sample chromatogram is presented in Figure 1 below;

Figure 1: Vaporization Potential Chromatogram of Vitamin E Acetate collected at 280ºC



The Chromatograph shows the range of thermal degradation vaporization byproducts that are generated at a given temperature. We have defined this profile of products that can be produced at a given temperature as the Vaporization Potential ("**VP**"). This profile is temperature dependent and so to further define the profile we use the nomenclature **VP^{xyz}** where the number "xyz" is the temperature that the profile was gathered, for example **VP^{280}** is the Vaporization Potential profile collected at 280ºC.

The **VP** profiles are representative of the gas phase above a vaporized sample and thus the profile of chemical agents that would be delivered to the consumer when the user draws in this vapor when using a heated device. This information is critical to understanding the potential pharmacological consequences of inhaling the chemical profile generated at a specific temperature from a specific composition from a vaporized sample. However, at the current time there are no established regulatory limits to the quantity of chemical agents a user can safely be exposed to when using a vaporized product. The development of these types of regulatory standards and the universal acceptance of such standards would require a lengthy and potential contentious legal and scientific based process. Although, we fundamentally agree that this type of process has significant merit, there is also merit in finding an alternate approach that could identify additives, such as Vitamin E Acetate, that have been clearly linked to adverse health events, specifically the **EVALI** hospitalizations and deaths observed in late 2019 and 2020. **EVALI** is the name given by the US Centers for Disease Control and Prevention ("**CDC**") to the dangerous, newly identified lung disease linked to vaping. The name **EVALI** is an acronym that stands for e-cigarette or vaping product use-associated lung injury.

In order to develop an approach for screening ingredients and mixtures intended to be used in vaporization devices for their potential to produce dangerous chemical agents, we have developed an alternate approach we refer to as Equivalent Residual Solvent Analysis ("**ERSA**").

3.0 Equivalent Residual Solvent Analysis

Most finished consumer products intended for human consumption which could include exposure to solvents as extraction agents or chemical cleaning agents are required to be tested for Residual Solvents. This Residual Solvent Analysis is a well established approach and section 467 of the US Pharmacopeia ("**USP<467>**") outlines limits for a variety of potential residual solvents. These limits are universally accepted as levels that consumer products should not exceed in order to be safe. We have observed that many of the chemical agents observed when collecting VP data are in fact included on the residual solvent list. Given this we developed a testing protocol where we place a test sample in an hermetically sealed glass headspace vial, then heat this to a defined test temperature, say 240ºC, hold it for 5 minutes, then cool it to room temperature and then analysed this material using a validated Residual Solvent Analysis method. The validated Residual Solvent Analysis method we employ is also a Headspace-GCMS method, however, in this case the vial is only heated to 95ºC and an external calibration curve is used to quantify the observed residual solvents generated from the heated incubation step. We refer to this approach as Equivalent Residual Solvent Analysis ("**ERSA**"). If the residual solvent analysis indicates that a sample would fail, then we conclude that the material should not be used in any product intended for inhalation that heats the material at a temperature above the temperature at which it failed.

Even though the stated approach will work at any temperature, we have found that as the temperature approaches 300ºC almost all materials we have examined fail and for practical considerations we have selected a temperature of 280ºC as the highest test point in this study. Furthermore, we also consider 240ºC to be the highest temperature that any vaporization device should be set as, as above this the concentrations of problematic thermal degradation products increase drastically. Given that, we typically recommend that a **VP^{240}** be the test temperature for routine screening and the **ERSA** analysis at 240ºC be used as the definitive pass fail test criteria. We have also observed that 180ºC is a temperature where Cannabinoids, typical Terpenes and Nicotine and related chemical compounds are effectively vaporized with little or no thermal degradation. Although we have observed a few problematic compounds begin to thermally degrade at temperatures as low as 210ºC, most do not begin to degrade until the temperature exceeds 220ºC. With this in mind we can imagine a public health message that strongly discourages any vaporization above 420ºF or 215.6ºC.

4.0 Summary of results for Vitamin E Acetate, Squalane and Squalene

In this report 3 ingredients have been examined: Vitamin E Acetate, Squalane and Squalene. Each of these have "failed" the **ERSA** assessment at 240ºC.

4.1 Vitamin E Acetate

The chemical structure of Vitamin E Acetate is presented below. This compound was a known additive in e-juice and Cannabis concentrates associated with many of the **EVALI** hospitalizations and deaths observed in late 2019 and 2020. It has been suggested that this compound is responsible for many of the adverse health effects in the **EVALI** event.

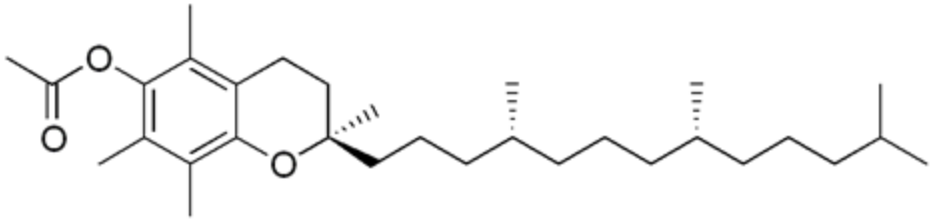


Figure 2: Chemical structure of Vitamin E Acetate

The VP profiles at a series of temperatures for Vitamin E Acetate is presented in Figure A.1 of Appendix A. The most dominant Oxidation products are Acetic acid and Formic acid and these are observed at sufficient quantities to have the compound fail the **ERSA** screening approach at 240ºC. This data is presented in Table A.2 presented in Appendix A.

4.2 Squalane

The chemical structure of squalene is presented in Figure 3 below. This is a possible ingredient that could be used in vaporization devices.

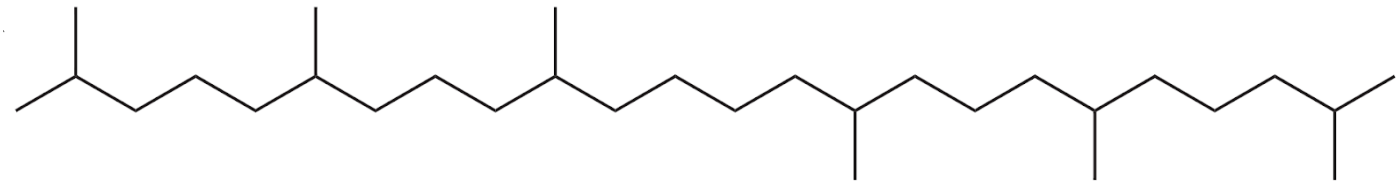


Figure 3: Chemical structure of squalane

The VP profiles at a series of temperatures for this compound is presented in Figure B.1 of Appendix B. The most dominant Oxidation products are Acetone, Methanol and Acetic acid and these are produced at sufficient quantities to have the compound fail the **ERSA** analysis at 240ºC. This **ERSA** data is presented in

Table B.2 presented in Appendix B. There are a diverse number of thermal degradation and oxidation products produced by squalane and based on this and the very high concentration of Acetone, Methanol and Acetic Acid we speculate that this additive would produce more diverse and adverse health effects as Vitamin E Acetate does.

4.3 Squalene

The chemical structure of squalene is presented in Figure 4 below. This is also a possible ingredient that could be used in vaporization devices.

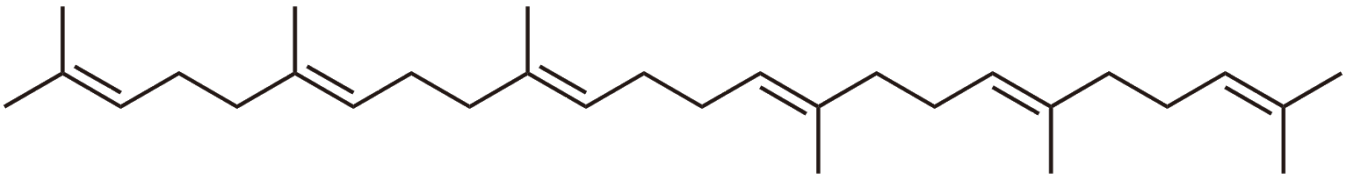


Figure 4: Chemical structure of squalene

The VP profiles at a series of temperatures for this compound is presented in Figure C.1 of Appendix C. There are a large number of Oxidation products generated including Acetone, Methanol, Acetic acid and Formic Acid that are produced at sufficient quantities to have the compound fail the **ERSA** analysis at 240ºC. This **ERSA** data is presented in Table C.2 presented in Appendix C. The diverse number of thermal degradation and oxidation products produced by squalene is of significant concern, especially, because this degradation begins at much lower temperature, 180ºC, than observed for other ingredients that we have studied previously. It is speculated that Squalene would produce more adverse health effects as Vitamin E Acetate does and that these adverse effects could begin at much lower vaporization temperatures.

5.0 Conclusion

The three compounds that we have examined in this report, Vitamin E Acetate, Squalane and Squalene each have failed the **ERSA** assessment protocol we have defined at 240ºC. Vitamin E Acetate has been identified as a problematic ingredient associated with **EVALI** hospitalizations and deaths. The data presented here suggests that Squalane and Squalene thermally degrade in a manner that produces higher levels of chemical agents than we observed for Vitamin E Acetate. From this, we speculate that these compounds could be more problematic than Vitamin E Acetate. However, it should be noted that these are speculations based on assumptions and this opinion is provided for discussion purposes only and is not intended to be a definitive statement on the safety of a given product or ingredient.

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Appendix A: Sample Results for Vitamin E Acetate

Client ID: n.a.

Supra Details: α-Tocopheryl acetate (Vitamin E acetate) (Sigma-Aldrich PN#R1030 Lot#LRAC1696)

Batch ID: 201022_VP-RS-quant-Oregon

Submission Date: 2020 October 15

Reporting Date: 2020 November 12

Analysis Date: 2020 October 22

Analyst: RJH / SRS

Authorized By: Ryan Hayward

Job Function: Laboratory Manager

Date Authorized: 2020 November 10

Signature: 

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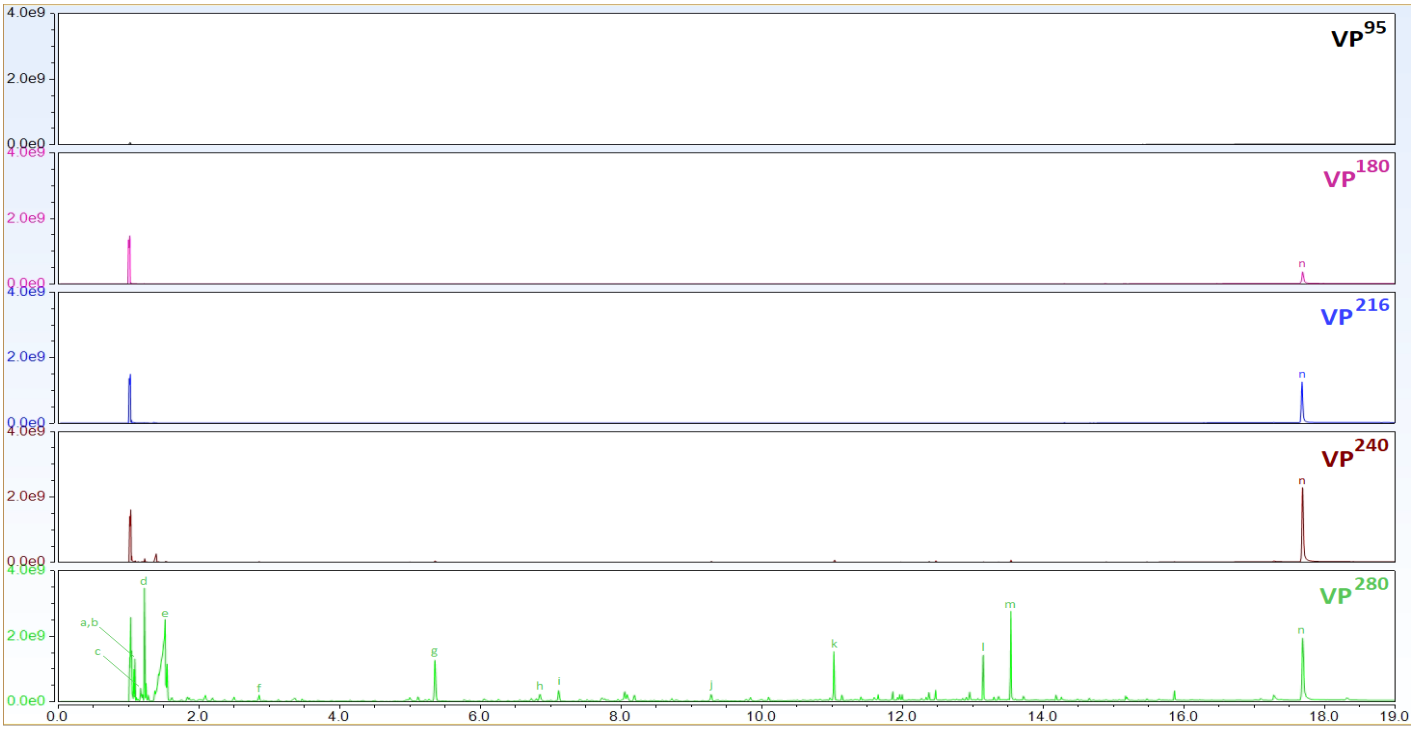
Figure A.1: Vaporization Potential Chromatograms For Vitamin E Acetate



Total Ion Chromatograms (TICs) of VP^{95}, VP^{180}, VP^{216}, VP^{240} and VP^{280} of vitamin E acetate. The chromatograms are scaled to the same *y*-axes.

Table A.1: Identified peaks for Vitamin E Acetate (qualitative profile)

Compound	Retention time (min)	Chromatogram label
methanol	1.07	a
acetaldehyde*	1.09	b
oxalic acid*	1.17	c
acetone	1.23	d
formic acid	1.50	e
hexanal*	2.86	f
6-methyl-2-heptanone*	5.36	g
2-nonanone*	6.85	h
4-methyl-3-pentenoic acid*	7.13	i
4,8-dimethylnonanol*	9.28	j
6,10-dimethyl-2-undecanone*	11.04	k
6,10,14-trimethyl-2-pentadecanone*	13.15	l
3-formyl-4-hydroxy-2,5,6-trimethylphenyl acetate*	13.54	m
vitamin E acetate	17.69	n

List of identified compounds in thermally-treated samples (see Figure 1 for labelled chromatograms). Compounds marked with an asterisk (*) were identified using NIST library matching (>800 SI and RSI). All other compounds were identified using analytical standards

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Table A.2: Equivalent Residual Solvent Analysis at 240ºC Vitamin E Acetate

	USP limit	VP^{240}
2-Butanone	5000	< 1000
2-Propanol	5000	nd
Acetone	5000	< 1000
Acetonitrile	410	nd
Benzene	2	nd
Cyclohexane	3880	nd
Ethanol	5000	< 1000
Ethyl formate	5000	nd
Hexane	290	nd
Isobutanol	5000	< 1000
Isopropyl acetate	5000	< 1000
Methanol	3000	< 600
Methylcyclohexane	1180	nd
n-Pentane	5000	< 1000
Acetic acid*	5000	> 10000
Formic acid*	5000	> 10000

Table 2 Description: Quantitated concentrations (parts-per-million [ppm] relative to original sample mass [Table 3]) of degradation products identified for each sample treatment at 240 ºC. Values were calculated using a full evaporation technique (FET) headspace method calibrated with residual solvent standards. Calibration ranges were 0.2x to 2x each analyte's USP limit. Results outside the calibration range are reported as greater than (>) or less than (<) the respective upper or lower limits of calibration. A semi-quantitative calibration was performed for formic acid and acetic acid. These compounds have been marked with an asterisk (*) and their results should be treated as estimates. Shaded values indicate failures.

Table A.3: Experimental details Vitamin E Acetate

After accurate weighing (Table 3), all samples were incubated in gas-tight headspace vials fitted with PTFE-lined silicone septa for temperatures ranging from 95 - 280 °C (*n* = 1/temperature). All incubations were performed for five minutes and included a blank vial alongside client formulations.

	Vaporization Potential ($VP^{°C}$)				
	VP^{95}	VP^{180}	VP^{216}	VP^{240}	VP^{280}
Vitamin E acetate (g)	0.0104	0.0098	0.0111	0.0111	0.0105

Masses of materials used for each temperature treatment. Samples were incubated at their designated temperature for five minutes to achieve an equilibrated headspace, from which 1 mL was sampled for analysis. Sampling was performed directly from the incubated vial to reflect delivery of volatiles into the headspace at respective temperatures.

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Appendix B: Sample Results for Squalane

Client ID: n.a.

Sample Details: Squalane (Sigma-Aldrich PN#PMR1417 Lot#LRAC4099)

Batch ID: 201022_VP-RS-quant-Oregon

Submission Date: 2020 October 15

Reporting Date: 2020 November 12

Analysis Date: 2020 October 22

Analyst: RJH / SRS

Authorized By: Ryan Hayward

Job Function: Laboratory Manager

Date Authorized: 2020 November 10

Signature: 

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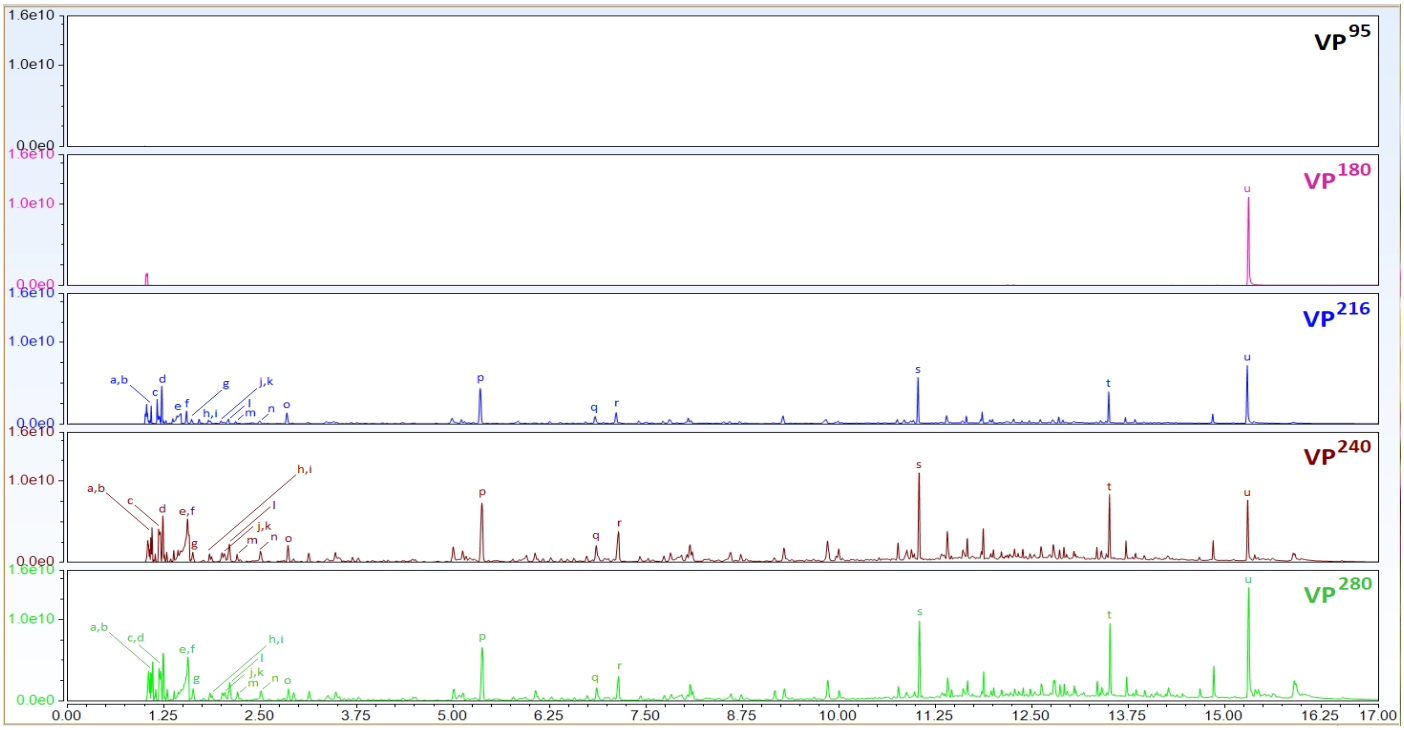
Figure B.1: Vaporization Potential Chromatograms For Squalane



Total Ion Chromatograms (TICs) of VP^{95}, VP^{180}, VP^{216}, VP^{240} and VP^{280} of squalane. See Table 1 for peak labels. The chromatograms are scaled to the same *y*-axes.

Table B.1: Identified peaks for Squalane (qualitative profile)

Compound	Retention time (min)	Chromatogram label
methanol	1.07	a
acetaldehyde*	1.09	b
oxalic acid*	1.17	c
acetone	1.23	d
acetic acid	1.50	e
2-butanone	1.55	f
4-methyl-3-pentenal*	1.62	g
3-methylbutanal*	1.85	h
3-methyl-2-butanone*	1.87	i
2-methylheptane*	2.00	j
2,2-dimethyltethrahydrofuran	2.04	k
2-pentanone*	2.10	l
acetol*	2.19	m
2-hexanone*	2.50	n
hexanal*	2.86	o
6-methyl-2-heptanone*	5.36	p
2-nonanone*	6.85	q
4-methyl-3-pentenoic acid*	7.14	r
6,10-dimethyl-2-undecanone*	11.04	s
2-nonadecanone*	13.52	t
squalane	15.31	u

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List of identified compounds in thermally-treated samples (see Figure B.1 for labelled chromatograms). Compounds marked with an asterisk (*) were putatively identified using NIST library matching (>800 SI and RSI). All other compounds were identified using analytical standards.

Table B.2: Equivalent Residual Solvent Analysis at 240ºC Squalane

	USP limit	VP^{240}
2-Propanol	5000	nd
Acetone	5000	> 10000
Acetonitrile	410	< 82
Benzene	2	nd
Cyclohexane	3880	< 776
Ethanol	5000	< 1000
Ethyl formate	5000	nd
Hexane	290	nd
Isobutanol	5000	nd
Isopropyl acetate	5000	nd
Methanol	3000	> 6000
Methylcyclohexane	1180	< 236
n-Pentane	5000	< 1000
Acetic acid*	5000	> 10000
Formic acid*	5000	< 1000

Quantitated concentrations (parts-per-million [ppm] relative to original sample mass [Table B.3]) of degradation products identified for each sample treatment at 240 ºC. Values were calculated using a full evaporation technique (FET) headspace method calibrated with residual solvent standards. Calibration ranges were 0.2x to 2x each analyte's USP limit. Results outside the calibration range are reported as greater than (>) or less than (<) the respective upper or lower limits of calibration. A semi-quantitative calibration was performed for formic acid and acetic acid. These compounds have been marked with an asterisk (*) and their results should be treated as estimates. Shaded values indicate failures.

Table B.3: Experimental details Squalane

After accurate weighing (Table B.3), all samples were incubated in gas-tight headspace vials fitted with PTFE-lined silicone septa for temperatures ranging from 180 - 300 °C (*n* = 1/temperature). All incubations were performed for five minutes and included a blank vial alongside client formulations.

	Vaporization Potential ($VP^{°C}$)				
	VP^{95}	VP^{180}	VP^{216}	VP^{240}	VP^{280}
Squalane (g)	0.0100	0.0094	0.0094	0.0103	0.0099

Masses of materials used for each temperature treatment. Samples were incubated at their designated temperature for five minutes to achieve an equilibrated headspace, from which 1 mL was sampled for analysis. Sampling was performed directly from the incubated vial to reflect delivery of volatiles into the headspace at respective temperatures.

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Appendix C: Sample Results for Squalene

Client ID: n.a.

Supra Details: Squalene (Sigma-Aldrich PN#S3626 Lot#MKCJ2769)

Batch ID: 201022_VP-RS-quant-Oregon

Submission Date: 2020 October 15

Reporting Date: 2020 November 12

Analysis Date: 2020 October 22

Analyst: RJH / SRS

Authorized By: Ryan Hayward

Job Function: Laboratory Manager

Date Authorized: 2020 November 10

Signature: 

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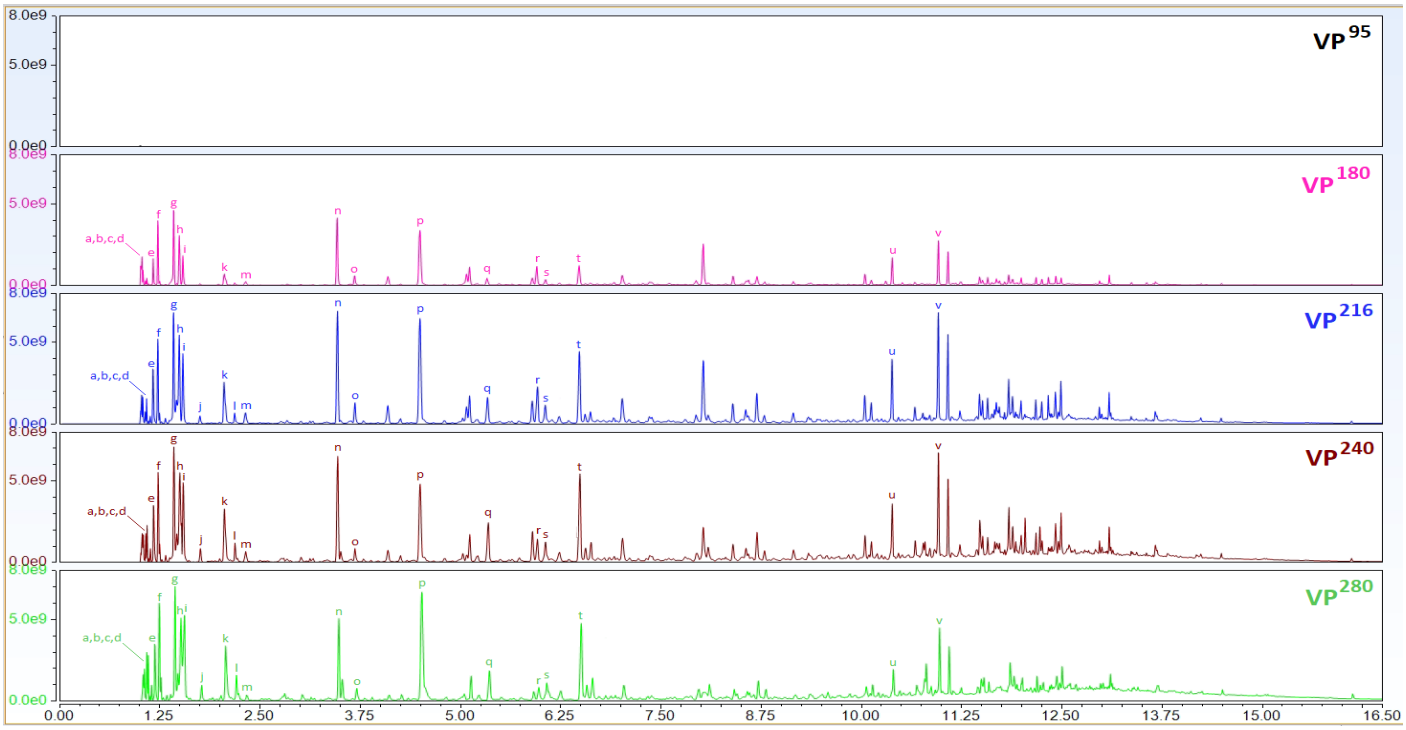
Figure C.1: Vaporization Potential Chromatograms For Squalene



Total Ion Chromatograms (TICs) of VP^{95}, VP^{180}, VP^{216}, VP^{240} and VP^{280} of squalene. See Table 1 for peak labels. The chromatograms are scaled to the same *y*-axes.

Table C.1: Identified peaks for Squalene (qualitative profile)

Compound	Retention time (min)	Chromatogram label
methanol	1.07	a
acetaldehyde*	1.09	b
glyoxal*	1.10	c
ethanol	1.13	d
oxalic acid*	1.17	e
acetone	1.23	f
methacrolein*	1.42	g
2-methyl-3-buten-2-ol*	1.50	h
3-buten-2-one*	1.54	i
3-hydroxy-3-methyl-2-butanone*	1.76	j
3-ethyl-2,2-dimethyloxirane*	2.06	k
1-hydroxy-2-propanone*	2.18	l
1-ethyl-5-methylcyclopentene*	2.32	m
3-methyl-2-butenal*	3.46	n
4-hydroxy-2-butanone*	3.69	o
3-methylcyclopentyl acetate*	4.50	p
4,4,5-trimethyl-1,3-dioxan-5-ol*	5.36	q
2,3-dimethyl-3-buten-2-ol*	5.95	r
6-methyl-5-hepten-2-one*	6.06	s
1-(1-butenyloxy)pentane*	6.49	t
citral*	10.04	u
3,6-dimethyloctan-2-one*	10.96	v

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List of identified compounds in thermally-treated samples (see Figure C.1 for labelled chromatograms). Compounds marked with an asterisk (*) were putatively identified using NIST library matching (>800 SI and RSI). All other compounds were identified using analytical standards.

Table C.2: Equivalent Residual Solvent Analysis at 240ºC Squalene

	USP limit	VP^{240}
2-Propanol	5000	< 1000
Acetone	5000	> 10000
Acetonitrile	410	nd
Benzene	2	0.4
Cyclohexane	3880	nd
Ethanol	5000	1382
Ethyl formate	5000	< 1000
Hexane	290	136
Isobutanol	5000	< 1000
Isopropyl acetate	5000	< 1000
Methanol	3000	> 6000
Methylcyclohexane	1180	< 236
n-Pentane	5000	< 1000
Acetic acid*	5000	> 10000
Formic acid*	5000	> 10000

Quantitated concentrations (parts-per-million [ppm] relative to original sample mass [Table 3]) of degradation products identified for each sample treatment at 240 ºC. Values were calculated using a full evaporation technique (FET) headspace method calibrated with residual solvent standards. Calibration ranges were 0.2x to 2x each analyte's USP limit. Results outside the calibration range are reported as greater than (>) or less than (<) the respective upper or lower limits of calibration. A semi-quantitative calibration was performed for formic acid and acetic acid. These compounds have been marked with an asterisk (*) and their results should be treated as estimates. Shaded values indicate failures.

Table C.3: Experimental details Squalene

After accurate weighing (Table 3), all samples were incubated in gas-tight headspace vials fitted with PTFE-lined silicone septa for temperatures ranging from 95 - 280 °C (*n* = 1/temperature). All incubations were performed for five minutes and included a blank vial alongside client formulations.

	Vaporization Potential ($VP^{°C}$)				
	VP^{95}	VP^{180}	VP^{216}	VP^{240}	VP^{280}
Squalene (g)	0.0096	0.0095	0.0102	0.0103	0.0111

Masses of materials used for each temperature treatment. Samples were incubated at their designated temperature for five minutes to achieve an equilibrated headspace, from which 1 mL was sampled for analysis. Sampling was performed directly from the incubated vial to reflect delivery of volatiles into the headspace at respective temperatures.

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END OF REPORT

Results reported by Supra Research and Development are representative of the materials as provided by the client.

Results are provided for information only and are not intended to comment on the safety of a given product.

Supra Research and Development shall retain all reports in a secure manner to prevent unauthorized access. Supra reserves the right to charge for the reissuance of reports in some instances.

Supra Research and Development will retain samples for a minimum period of 45 days following the release of the report. After 90 days following the release of the report samples are subject to disposal.

Supra Research and Development Inc.
#106 - 2293 Leckie Road, Kelowna, BC.,V1X 6Y5
Email: R.OB@SupraRnD.ca
1-250-878-4711

November 21, 2020

RE: 845-025-3265 Inhalable Cannabinoid Product Processor Requirements

To whom it may concern;

I am writing to provide unsolicited scientific input relating to "OREGON LIQUOR CONTROL COMMISSION CHAPTER 845 PROPOSED AMENDMENTS" and more specifically Section 2(b) that bans the use of (A) Squalene; (B) Squalane; (C) Vitamin E Acetate; (D) Triglycerides, including but not limited to Medium-Chain Triglyceride (MCT) Oil; or (E) Propylene Glycol, "...for use in a product intended for human inhalation".

Our company is an Canadian based analytical research firm that has been actively involved in organizations such as AOAC International and ASTM International that develop standards relating to consumer product safety. At AOAC international we have played a critical role in the initiation of a new "Heated Inhalant Science Program" ("**HISP**") and are a founding pioneer member of the Cannabis Analytical Science Program ("**CASP**"). At ASTM International we are also actively engaged in Committee D37 on Cannabis ("**ASTM D37**"). Through the ASTM we are actively engaged in the development of a new standard to evaluate potential ingredients that could be used in devices used to create vapors for inhalation, more specifically, we have developed a testing protocol to determine if ingredients or mixtures are likely to thermally degrade into hazardous chemical agents when heated.

Through the use of our testing protocol we can get an estimate of the nature of thermal degradation products that can be produced when heated to a series of temperatures commonly obtained in vaporization devices. Recently we have generated a report for the Oregon Liquor Control Commission where we examined Squalene, Squalane and Vitamin E Acetate using our approach, This report is attached as a component of this submission. Each of the compounds we examined failed our testing protocol and both Squalane and Squalene appeared to generate thermal degradation products that would make them relatively more dangerous than Vitamin E Acetate. Further, they generated some similar thermal degradation chemical agents to Vitamin E Acetate and it could be speculated that their observed toxicity could appear similar. Our data supports the inclusion of the three compounds we mentioned in the set of materials banned "...for use in a product intended for human inhalation".

Supra Research and Development Inc.
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1-250-878-4711

We would further recommend that the onus be placed on the producer to show evidence that the ingredients or mixtures that are intended "...for use in a product intended for human inhalation", do not generate hazardous substances when heated the temperature of intended use. The testing protocol we have developed could meet this requirement and is simplest enough that any lab who currently tests materials for Residual Solvents could also implement this testing protocol.

We are committed to helping regulatory bodies and processors develop protocols that ensure consumer products are as safe as possible. If there is anything we can add to the discussion that would help you in your task, please feel free to contact me at the email or phone number listed in the page header.

Sincerely,

Rob O'Brien, B.Sc., PhD
CEO & CSO, Supra Research and Development

From:	Gary Kaminsky
To:	Sheehy TJ * OLCC
Cc:	OLCC.Rulemaking * OLCC; Michael Bronstein
Subject:	Re: ATACH comments
Date:	Monday, November 23, 2020 3:49:58 PM
Attachments:	ATACH OLCC Chapter 845 comments (final).pdf

Gary S. Kaminsky, Esq.
Chair, ATACH CBD Task Force
Founding Member, ATACH Cannabis Beverage Council

gary@atach.org
610-724-9259

On Nov 23, 2020, at 6:17 PM, Sheehy TJ * OLCC <TJ.Sheehy@oregon.gov> wrote:

Gary -

We aren't able to open the attachment you included in your email. When trying to open we get an error message that the file format is incorrect or the file is corrupted. Could you please try regenerating and resending the PDF?

Thanks,

TJ Sheehy
Director, Analytics & Research
Oregon Liquor Control Commission
9079 SE McLoughlin Blvd., Milwaukie, OR 97222
Cell: 503-250-3396 | Office: 503-872-5017

-----Original Message-----
From: Gary S Kaminsky [mailto:gary@atach.org]
Sent: Monday, November 23, 2020 2:50 PM
To: OLCC.Rulemaking * OLCC <OLCC.Rulemaking@oregon.gov>
Cc: Michael Bronstein <michael.l.bronstein@gmail.com>
Subject: ATACH comments

Gary S. Kaminsky, ESQ
Chair, ATACH CBD Task Force
Founding Member, ATACH Cannabis Beverage Council

gary@atach.org
(610) 724-9259

Follow me on Twitter @ gskaminsky

Typed on my iPhone, please excuse any typos.

November 23, 2020

VIA E-Mail
OLCC.rulemaking@oregon.gov

Oregon Liquor Control Commission
9079 SE McLoughlin Ave
Milwaukie, ORG 97222
Attn: Madeline Kane

Re: Letter of Support to Chapter 845 OLCC Notice of Proposed Rulemaking for Inhalable Cannabinoid Products that use Non-Cannabis Additives

Dear Mrs. Kane:

The American Trade Association for Cannabis and Hemp ("ATACH") is a 501(c)6 trade organization that promotes the expansion, protection and preservation of businesses engaged in the legal trade of industrial, medical, and recreational cannabis-based and hemp-based products. ATACH has been named "Trade Association of the Year" and "Corporate Grassroots Organization of the Year" by *Campaigns & Elections* magazine. ATACH's membership includes some of the most influential businesses as well as state, national, federal and international cannabis trade associations and organizations. ATACH has also entered into a historic memorandum of understanding with ASTM International to develop standards for the cannabis industry and has recently launched a pilot Cannabis Certification Program in conjunction with ASTM International and the Policy Center for Public Health and Safety to standardize the cannabis industry.

In September 2020, ATACH launched a Task Force to facilitate the harmonization of emerging cannabis-related laws and regulations and provide an industry response to marketplace issues surrounding CBD and other cannabinoids. The Task Force is led by legal compliance professionals from the country's top hemp and marijuana operators, representatives from financial institutions and testing laboratories, in addition to medical experts and mainstream stakeholders.

We submit this letter of support on behalf of our members.

ATACH commends the OLCC for creating a foundation for non-cannabis additive standardization framework applicable to both hemp and marijuana products. Below are three points that ATACH would like to highlight about the regulations.

Proposed Amendments to 845-025-7000, 7120, 7160, and 7190

In light of the EVALI outbreak of 2019, ATACH strongly supports Oregon's approach to promote more transparency concerning non-cannabis additives by affirmatively distinguishing between cannabis and non-cannabis additives and requiring pre-approval for labels of inhalable cannabinoid products containing non-cannabis additives. Consumer safety and transparency is paramount and these changes permit consumers to know the non-cannabis additives they are inhaling and make an informed decision based on publicly available information. Requirements for pre-approved labels, combined with maximum concentration limits of non-cannabis ingredients will help ensure better control over harmful non-cannabis additives and an expedited process to identify and remove those harmful additives from the marketplace.

Similarly, ATACH supports OLCC's recognition that a substance's GRAS designation for use in foods is irrelevant to determine its safety for products meant for inhalation. This important distinction, overlooked by many states, recognizes that the human digestive system and the human respiratory system operate differently.

Proposed Rule 845-025-3265 and Proposed Update to Rule 845-025-3220

ATACH supports this proposed rule and the clear prohibition against certain ingredients being used in inhalable cannabinoid products that are most likely to cause acute or chronic harm when exposed to vaping conditions and inhaled. ATACH supports OLCC's initial list of prohibited ingredients which includes squalene, squalane, vitamin E acetate, triglycerides including MCT oil, and propylene glycol. The new rule creates a workable framework for the OLCC to quickly take action to prohibit additional substances should additional credible research arise.

While ATACH supports a reasonable grace period of manufacturing and sales, the regulations permit prohibited materials during this grace period which ends July 1, 2021. ATACH believes that consumers would be best served if these prohibited materials are not be allowed during this grace period, or in the alternative ATACH would like to see a shortened grace period, given their known risks for causing acute and chronic harms.

OLCC's Distinction amongst Different Additives

ATACH would like to see OLCC continue to drive the distinction between different categories of cannabis additives including (i) cutting agents and thickeners, (ii) flavoring derived from non-cannabis sources, and (iii) pesticides. While all of these substances can be considered additives, they must not be conflated into one category given the different uses for each. Not only will differentiating between these substances help promote

standardization and harmonization across the industry, it will also assist OLCC to quickly identify dangerous substances and take swift action to remove them from the marketplace.

ATACH thanks the OLCC for this opportunity to submit comments and looks forward to further discussion on these important issues.

Sincerely,

Michael Bronstein
President and Co-Founder
American Trade Association
For Cannabis and Hem

From: Karissa Sevier
To: OLCC.Rulemaking * OLCC
Subject: Response
Date: Monday, November 23, 2020 2:02:25 PM

I work for a company that is licensed by the OLCC recreational marijuana program and manufactures several vape brands here in Oregon. I am writing in opposition to the proposed amendments new regulations for vape products in Chapter 845.

The proposed rules will result in regulations that will ban nearly 40% of the products that we manufacture and thereby puts the jobs of many of my co-workers in jeopardy. The rationale for the change in rules does not appear to be consumer driven, endorsed by the industry at large, nor backed up by compelling evidence for product safety. As a result, I respectfully request that you strongly consider redeveloping the rules to be aligned with consumer demand, utilize sound evidence based in science in determining which additives to ban, and not overly onerous to compliant businesses that are operating in good faith in the Oregon cannabis market.

In short, the proposed amendments to marijuana additives will limit consumer choices and result in the destruction of cannabis jobs. The OLCC should strongly consider engaging the cannabis industry in the development of rules that will provide protections for consumer safety, consumer choice, and only ban additives that are backed by a reasonable threshold of evidence shown to pose a threat to consumer health.

Sincerely,
Karissa Sevier

Sent from my iPhone

From: Autumn Bell
To: OLCC.Rulemaking * OLCC
Subject: Response
Date: Monday, November 23, 2020 2:02:12 PM

I work for a company that is licensed by the OLCC recreational marijuana program and manufactures several vape brands here in Oregon. I am writing in opposition to the proposed amendments new regulations for vape products in Chapter 845.

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Sincerely,

Autumn Bell

From: Adam Smith
To: OLCC.Rulemaking * OLCC
Subject: Vape Additive Rules Comments
Date: Friday, November 20, 2020 4:16:18 PM

To Whom It may concern.

My name is Adam Smith, I am the CEO/Owner of a Licensee that manufactures several vape brands here in Oregon. We employ just over 30 people in Oregon and sell just over $10M a year of products across vapes and flowers in Oregon. I am offering testimony in opposition to the proposed amendments in Chapter 845. These rules, while well intentioned, are misguided and will have severe impact on consumer choice, limitations of products available in the legal/rec market and major economic impact on small businesses. The rules as written are a defect ban of vapes containing additives and therefore a punitive assessment against our business. It seems the OLCC is blaming licensed processors for a health crisis, which by the FDA's own investigations, was caused by Vitamin E acetate primarily in the illegal/illicit markets.

The goal of legalizing and regulating cannabis in Oregon was to eliminate the illicit market and provide regulation around the orderly manufacturing, processing and distribution of the cannabis products in the state. These rules risk taking a major setback in achieving that goal and the achievements by the OLCC over the last several years. Markets are driven by consumers and Oregon consumers have spoken with their wallets - flavored and botanically enhanced vaporizers are what consumers want in Oregon. The best-selling vaporizer products in Oregon are ALL either botanically derived or flavored vaporizer products. https://www.headset.io/the-best-selling-cannabis-products/oregon-vapor-pens

The OLCC rules committees, through several statements and meetings, have a false belief that there is no consumer preference or demand for flavored/botanical vape products in Oregon and that companies offering flavored or botanically enhanced vapor products can simply shift to 100% cannabis offering and consumer purchasing behavior will follow. That is a misguided belief on several fronts. Consumers demand flavored and botanically enhanced products because they prefer these products. Consumers are also clearly aware that these are not 100% cannabis products because OLCC rules require manufacturers to clearly state “Cannabis Extract with Non-Cannabis Derived Terpenes” Or “Cannabis Extract with Natural Flavorings” on the front of every package. Furthermore, during the vape crisis temporary ban we did not see ANY movement from flavored to 100% products (which we also sell), the sales of the flavored/botanical products simply stopped.

There are also several problems with the economic impact assessment of this ban. Primarily that the loss of market share in vape carts will be made up through price increases or shifting demand to other products. Again, during the vape ban, that did not happen. As far as price

increases, we know there is a direct relation between the price of a product and the volume sold in the Oregon market. The price of 100% cannabis terpenes will skyrocket as soon as this ban is put in place (which we saw happen during the temporary ban). The wholesale price of vapes along with the retail price will go up, cutting into demand by driving consumers out of the legal market and collapsing this category. The vape market losing up to 25% of its products will impact the wholesale flower and trim market, creating yet more oversupply in this tier of the supply chain. This will impact all segments of the market as a large portion of the revenue does not shift to another category, it simply disappears. The economic statements in the proposed rule documents are littered with false assumptions and a clear lack of knowledge around market dynamics. Banning botanical terpenes will be a financial disaster in the making for a large section of the industry.

Our sales are driven by consumer choices and preference, we will not simply be able to shift demand from flavored products/botanical products to 100% cannabis vapes and as a result we will lose about 40% of our revenue. We can not afford to lose 40% of our revenue and we will have no choice but to respond by laying off 12 - 15 people. Furthermore, our flavored/botanical vape products alone contribute over $4M in tax revenue to the state. That tax revenue will disappear, it will not shift to a different category.

Next, limiting product choices with proven consumer demand does nothing but undermine the legal market and drive consumers back to the illicit market. The entire purpose of legalization was to eliminate the illicit market. Prohibitionist rules like the ones proposed will do nothing but punish legal licensed producers and push consumers into the illicit market. The stated purpose of the limitations and new labeling rules are to keep consumers safe from issues like VAPI or other health crisis but pushing consumers to buy products they want from unregulated sources will do exactly the opposite of the intention of these rules. Consumers want flavorful and affordable vapes, if we do not provide those legally, they will buy them off the internet or street corner and be more exposed to contaminants and chemicals which according to the FDA likely caused VAPI in the first place.

In short, we believe that the proposed rules create a de-facto ban on vape products containing additives, limit choices for consumers many of whom favor products with additives in them, create restrictions in the market without evidence or coherent rationale for the banning of certain additives, and require the disclosure of Intellectual Property which is uncharacteristic of any other cannabis market in the country (or even category of products in Oregon). The impact of this will be massive harm to vape providers as a whole and impact to downstream suppliers of raw materials and the unintentional but inevitable outcome of forcing consumers out of the recreational market back into the dangerous illicit market. All this for no clear benefit to the State, the OLCC, consumers or businesses.

I implore you to stop the current process and start over with a well-crafted and narrow

definition on what the OLCC is trying to accomplish, which in itself is not even clear in these rules. Please do not move forward with these rules as written.

Thank you,
Adam Smith
CEO, Avitas Oregon Holdings.

P.S. The OLCC representatives, on numerous occasions, have commented about how few people from the industry or consumers are commenting on these rules as some type of proof that the changes are welcomed by the industry. Or, that certain members of the industry fully support these rules. This is completely ignoring the fact that most businesses are struggling to stay alive in a pandemic and have zero time to pay attention to these proceedings and that most consumers have no idea the discussion about banning their favorite products is taking place. Those outspoken companies in the industry who are in favor of these rules do so with the misguided opinion that it will help their business because they have made a choice to be 100% cannabis. They are thinking "Gee if only those flavored vapes were banned, I'd sell more of my product". The OLCC should not be the arbiter of business models, nor should they be choosing winners in the market, that is up to consumers, who have spoken loudly about their preferred products.

From: Erin Tangman
To: OLCC.Rulemaking * OLCC
Subject: Vape Cartridge Regulation Proposal
Date: Monday, November 23, 2020 2:34:05 PM

To Whom it May Concern;

I am a consumer of vape products licensed by the OLCC recreational marijuana program and I am writing in opposition to the proposed amendments new regulations for vape products in Chapter 845.

The proposed rules will ban flavored vape cartridges which contain a small amount of MCT oil in them. As a consumer, I enjoy the ability to make my own decisions about the products I consume and do not understand why the OLCC is taking such a dramatic step to ban PG and MCT in all regulated cannabis vape products. Other non-cannabis vape products (such as nicotine vapes) contain much higher amounts of PG and MCT than cannabis vape products and will still be sold in vape shops and convenience stores, yet cannabis products with much lower amounts of PG or MCT will be banned. Surely you can see how this is not logical.

As a consumer I want access to a variety of flavored vapes. I suggest that we have regulations that offer a wide array of products for consumers and let us decide which products we want to buy.

Sincerely,

Erin Tangman
(503)858-5601