PUBLIC HEALTH DIVISION
Office of the State Public Health Director
Kate Brown, Governor

800 NE Oregon Street
Portland, OR 97232
Voice: (971) 673-1222

DATE: March 16, 2022

TO: Hearing Attendees and Commenters –
Oregon Administrative Rules chapter 333, divisions 7 and 64, "Marijuana and hemp testing and laboratory accreditation standards"

FROM: Brittany Hall, Hearing Officer

cc: Megan Lockwood, Manager
Oregon Medical Marijuana Program
Public Health Division, Oregon Health Authority

Travis Bartholomew, Manager
Oregon Environmental Laboratory Accreditation Program
Oregon State Public Health Laboratory, Oregon Health Authority

SUBJECT: Presiding Hearing Officer's Report on Rulemaking Hearing and Public Comment Period

---

Hearing Officer Report

Date of Hearing: February 16, 2022, via Microsoft Teams

Purpose of Hearing: To receive testimony regarding the Oregon Health Authority (OHA), Public Health Division, Oregon Medical Marijuana Program's (OMMP) and Oregon State Public Health Laboratory's (OSPHL) permanent adoption, amendment and repeal of Oregon Administrative Rules in chapter 333, division 7 and 64 related to cannabis testing, cannabis laboratory accreditation and concentration limits.

The amendment of rules aims to address concerns raised in the Oregon Secretary of State audit report on marijuana dated January 2019. A highlight of the report indicated that Oregon should consider requiring testing for heavy metals and microbiological contaminants, enhance test oversight and ensure labs meet accreditation standards. These rule changes propose the addition of testing for heavy metals starting January 1, 2023, mycotoxins starting July 1,

2022, and microbiological contaminates starting January 1, 2023, on marijuana items and industrial hemp-derived vapor items sold in Oregon. To adopt these changes and not impart a large fiscal impact, OHA is seeking to change rules related to sampling to ensure representative sampling is still performed. The definition of a harvest lot is being expanded to 7-calendar days and a batch could consist of up to 50.0 pounds marijuana for testing starting July 1, 2022. Rules around control studies are being proposed to be repealed.

These rule changes also move towards a testing scheme where the end product is tested. Inhalable cannabinoid products are being created as a new sub-category of cannabinoid products to align with OLCC rules. Testing will be required for inhalable cannabinoid products once they are finished and before being transferred for retail sales. Another change that is occurring within the product category is around baked edible products. These products will be allowed to leave the process lot unbaked and in their final form for purposes of sampling and allow the samples to be baked and taken by the testing laboratory. The sampler will be required to remain at the processing site from the time the samples are selected to the time they are baked to ensure chain of custody of the items. No additional ingredients may be added to the fresh baked goods.

Additional standards for accredited cannabis laboratories are being proposed that include the adoption of stricter standards and methods to ensure testing performed is accurate and more consistent between the laboratories, prescribing limit of quantitation levels and quality control acceptance criteria and of sample homogenization.

Hearing Officer: Brittany Hall

Testimony Received: Six individuals provided oral testimony at the hearing. These comments are briefly summarized below.

Victor Hernandez, Firecreek Farms

Mr. Hernandez spoke about his concerns with these proposed rules being multifaceted. He stated that he has been in other states where microbial testing has been required, and from his experience, has seen certain end products of the crop which would have visible mold that would test through fine and those without visible mold would test hot for microbial. He questions what exactly the microbes they are testing for and if it is necessary.

He stated that his other concern is that right now most farms are struggling to make rent and stay afloat in a market that is oversaturated and not working as well as it could be. His is already limited as to what he can get tested based off of strains and pricing and cannot see as a farm that it would be beneficial to add more testing to that. His farm is limited in having diversified product due to the cost of testing even though they are in a market that requires diversification as far as strains go. He stated that he appreciates the 50lb limit but that it only covers one strain and not multiple strains. He expressed concern that these changes come at a really horrible time to put more financial burden on his business.

Agency response:
Thank you for your comments. The agency has chosen to focus microbiological testing on pathogens that are known to be harmful. That includes pathogenic Aspergillus flavus, A. fumigatus, A. niger and A. terreus, Shiga toxin-producing Escherichia coli and Salmonella species.

A harvest lot of marijuana does not need to be strain specific and all tests, except testing for potency, may be composited across the different strains harvested within a seven-calendar day period. During the rules advisory committee meeting the cost of the new tests was discussed. It was determined that through changes being made to the way items are sampled will help offset the cost. The addition of mycotoxins, heavy metals and microbiological contaminants will increase the public health and safety of cannabis items for consumers.

Steve Penman, Sugartree Farm

Mr. Penman stated that there are a lot of unknowns around the microbials and that he is unsure about the colony counts that the OHA is imposing. He expressed concern that if they test a 50lb batch and one flower might have some mold in it that would have been found by the consumer before they smoke it. He asked if they lose the 50lbs or have to mitigate that.

Mr. Penman also stated that he's heard from growers in Colorado that the smoke and ash from wildfires, which are also happening in Oregon and specifically Jackson County where his farm is located, can contribute to the heavy metals count and failure. He recommended that another working group is started to find out what the cost and unknowns are of the new testing and revisit this in 2025. He opined that adding any more cost to something that is working right now would be fiscally damaging to his company.

Mr. Penman also added that they use irrigation water and are at the end of the line. All of the people behind them use flood irrigation, so they are subject to whatever comes along the line and so much is out of their hands. He again suggested that a study group needs to look at this, and that Oregon not jump into these new requirements now just because other states are.

Agency response:
Thank you for your comments. OHA already held a workgroup and two rule advisory committees to discuss the addition of mycotoxin, heavy metals and microbiological contaminants and does not see the need to have another. Concerned raised about the impacts of things like wildfires could have on heavy metal counts was discussed. Soil may be tested at any time to determine if any contaminants are present. The agency has chosen to focus microbiological testing on pathogens that are known to be harmful. That includes pathogenic Aspergillus flavus, A. fumigatus, A. niger and A. terreus, Shiga toxin-producing Escherichia coli and Salmonella species. A sample fails if the presence of any of the species is detected in one gram of sample. It is a business decision regarding the size batch a grower or producer submits for testing. A 50.0 pound batch is the maximum size that may be submitted for testing. A smaller batch size may be submitted.

Mitra Sticklen, OM Extracts

Ms. Sticklen stated that her company is in support of the added testing proposed for heavy metals, mycotoxins and microbiological contaminants on marijuana items as well as the industrial hemp derived vapor items. They suggest adding all industrial hemp items to these testing requirements.

She stated that they support the shift in sampling protocols, as well as the expansion of harvest lots to 7 calendar days and up to 50lbs.

They are also in support of repealing the control study rules, especially because the control study costs have created a financial barrier for her company to launching new safely tested and consistent extracts. She opined that this update would continue to ensure customer safety while reducing the financial burden for producers and processors.

Ms. Sticklen commented that her company also proposes a reduction in the maximum allowable limit of ethanol in marijuana extract. She stated that the

current allowable limit was raised when recreational went into effect. Her company believes that the ethanol limit should be more reflective of other states that have much lower limits, especially when it comes to any inhalable extract, as consuming large amounts of ethanol can be dangerous and can have adverse medical effects.

Ms. Sticklen also submitted written comments that are attached to this report as Exhibit 1.

Agency response:
Thank you for your comments. OHA only has authority to adopt testing standards for marijuana items and industrial hemp-derived vapor items. The Oregon Department of Agriculture sets standards for testing for all other industrial hemp items.

OHA will consider your comments about adding ethanol and sulfur in a future rulemaking.

Jamie Toth

Ms. Toth stated that she first wrote about lab issues with THC potency testing in 2019 and was told by someone in the industry to not write about it. When the issue came up again recently, she didn't let it go. She has analyzed 250,000 records and interviewed lab personnel from nearly every lab in Oregon, as well as others in the cannabis industry to try and understand the issue.

Ms. Toth opined that if a lab, processor, farm or dispensary is willing to fudge THC potency to make extra money, they will be willing to lie about other aspects of testing. She also opined that the erosion of trust in laboratory results is the real issue that needs to be addressed and these rules are not effective at addressing those issues. She stated that labs, processors, retailers and consumers are unprotected against bad actors without audit strategies that work during times of pandemic and other crises. Tightening restrictions on testing thresholds, adding tests or giving general guidance when sampling technique is meaningless without a comprehensive audit strategy or a centralized effort to continuously monitor accuracy and quality. She further opined that increasing the batch size will only compound the current testing issues.

Ms. Toth also submitted written comments that are attached to this report as Exhibit 2. Please note that some of the images and graphics in Ms. Toth's written

comments are not available in the attached Exhibit. Please contact publichealth.rules@dhsoha.state.or.us to receive a complete copy of these comments.

Agency response:
Thank you for your comments. A batch size of 50.0 pounds is the maximum allowable batch size. Smaller amount may be submitted for testing. Oregon is seeking to align testing rules with California and consulted with California on increasing the batch size to 50.0 pounds. It was indicated that the average size submitted for testing is closer to 25 pounds. Regulations already require representative sampling which should not result in a diluted sample.

Adoption of rules around Laboratory Control Standards is intended to tighten laboratory quality control data and bring greater accuracy and consistency between laboratories' testing results.

Many of the written comments made are not relevant to this rule making nor fall under OHA jurisdiction. OHA does not have the ability to change labeling rules, perform data checks in Metrc, or establish a reference lab. Labeling rules and Metrc data fall under the OLCC. A reference lab would need to be authorized through the legislature.

Jill Ellsworth, Founder and CEO, Willow Industries

Willow Industries has invented, developed and commercialized a kill step technology using ozone gas for the cannabis industry. They operate in 26 states and look to bring technology and services to Oregon.

Ms. Ellsworth's comments address modifying the language for failed test samples, OAR 333-007-0450. She proposes new language stating that marijuana that fails microbiological testing should be allowed to be sterilized using methods that do not change its form. She stated that the current language only contemplates methods that extract into concentrates after a failed test. She believes that adding the testing is great for consumer safety, but wants to make sure that the way the rule is written it does not lead to economic losses for cultivators. If a cultivator can only extract a batch of failed flower, that can lead to potential economic losses.

Since there are multiple processes (ozone and irradiation) that can sterilize marijuana without changing its form, Ms. Ellsworth requests this language to be

changed to allow either type of processes in response to a failed test. Meaning the cultivator can use a decontamination process to clean the flower or they can extract the flower. She stated that many states have adopted these regulations.

Ms. Ellsworth also submitted written comments that are attached to this report as Exhibit 3.

Agency response:
Thank you for your comments. OHA agrees with the proposed recommendation of allowing marijuana and usable marijuana to be remediated without changing its form. The OHA will be modifying OAR 333-007-0450(6) to allow for remediation through sterilization for marijuana and usable that fails microbiological testing. Sterilization is defined as the removal of all microorganisms and other pathogens from a marijuana item or industrial hemp-derived vapor item by treating it with approved chemicals, subjecting it to high heat or other process. This definition does allow for the use of ozone.

Jason Lampman, State 3 Farms

Mr. Lampman stated that State 3 Farms is an organic micro-tier farm. He further stated that his understanding is that the fungi and bacteria that grow in a culture that are harmful are the toughest to grow in a culture, and that hopefully the qPCR testing solves that. He looked at the detailed Secretary of State's audit to see why these tests were being added. He noted that it stated in the audit that they were going to perform a thorough study on the potential impacts of heavy metals and contaminants in marijuana products and was unable to find that study anywhere for Oregon or any other state.

He commented that his main concern is the economic impact of the new requirements. His farm is looking at $200-500 extra on a test or a 50-60% rise in testing costs. This will be a financial burden on his business.

Mr. Lampman cited the Administrative Procedures Act, ORS 183.336 and 183.540 for the reduction of economic impact on small businesses. "If a rule has a negative impact, the agency shall reduce the economic impact by establishing different compliance requirements for small businesses, exempting small businesses, or otherwise establishing less intrusive and less costly alternatives for small businesses."

Mr. Lampman suggested that there be a way that farms in good standing or small micro-tiers could test every other month or twice a year in order to alleviate the financial burden.

Agency response:
Thank you for your comments. The agency has chosen to focus microbiological testing on pathogens that are known to be harmful. That includes pathogenic Aspergillus flavus, A. fumigatus, A. niger and A. terreus, Shiga toxin-producing Escherichia coli and Salmonella species. A sample fails if the presence of any of the species is detected in one gram of sample.

The SOS recommended that a thorough study be performed. In the response to the SOS, OHA stated that "While OHA agrees with this recommendation, there are currently no resources to conduct such a study. Resources would need to be allocated for this study to occur. In the absence of dedicated resources to conduct a thorough study, OHA will reach out to other states with legalized marijuana to request their data related to testing for specific microbiological and heavy metal contaminants. OHA can also convene a rules advisory committee to seek guidance on testing for microbiological and heavy metal contaminants in marijuana products." OHA followed through these steps.

Smaller growers were considered during the rule making process. During the rules advisory committee meeting the cost of the new tests was discussed. It was determined that through changes being made to the way items are sampled will help offset the cost. In addition, the timeframe for a harvest is being expanded from 72-hours to 7-calendar days to assist smaller growers in being able to submit larger batch sizes. A harvest lot of marijuana does not need to be strain specific and all tests, except testing for potency, may be composited across the different strains harvested within a seven-calendar day period. The addition of mycotoxins, heavy metals and microbiological contaminants will increase the public health and safety of cannabis items for consumers.

Other Comments: Fourteen individuals submitted written comments prior to the deadline of 5:00 PM on February 21, 2022. Their comments are briefly summarized below.

Alex Hoggan, Owner and Director of Business Operations, ChemHistory

Mr. Hoggan wrote that since there isn't data to support the new tests, he cautions not to over test. In order to prevent over testing of products and keep costs

down, Mr. Hoggan wrote to suggest "that if a producer tests their plant material for Mycotoxins and heavy metals that when it goes to processing they would only need 1 test to check for each of those analytes. If there was a positive hit then a confirmation test would be required. If a producer does not have the plant material tested and goes straight to processing then a prime and field duplicate would be required."

Mr. Hoggan's written comments are attached to this report as Exhibit 4.

Agency response:
Thank you for your comments. The Oregon Health Authority considered over-testing when drafting the proposed rules. Testing a primary and field duplicate is required to be performed on the end product that will be going to market. For batches of concentrates, extracts, finished inhalable cannabinoid products, and industrial hemp-derived vapor items over 12 kilograms a replicate sample would need to be tested for solvents and potency. No intermittent testing is required. This is to ensure the end product is safe in its final form, ready for use by a consumer.

Christian Hageseth, Chief Operating Officer, VIST Labs

Mr. Hageseth's written comments address his opinion that "most participants in the [cannabis] industry are trying to 'Get by – not Comply.' Compliance often requires someone to validate that compliance, and the participants have found many ways around complying." He further wrote that "the lack of compliance is affecting our customers' health and safety" and that "the revised rules are leaving out a majority of contaminants that will slip through the cracks and get more people sick." Mr. Hageseth's written comments detail the health risk to consumers from inhaling microbially contaminated cannabis.

Mr. Hageseth stated in his written comments that "[VIST Labs is] requesting the State of Oregon to consider adopting the same standards that the FDA and FTC use today for food, pharmaceutical, and medical products which will likely be imposed upon federal legalization." He opined that "an early adoption is critical for all cannabis growers to begin accommodating these changes so that they are prepared and already in line with regulations. This ensures the safety of consumers and the integrity of the cannabis industry in Oregon."

Mr. Hageseth's written comments detail the specific standards that VIST labs is proposing related to:

1. Protection of consumers' health by "implementing microbial testing standards including Total Yeast and Mold Counts [TYMC] and Total Aerobic Counts [TAC] and provide a maximum threshold of 10,000 CFU/g that would occur at representative sampling for state testing before it is packaged and sent to retailers";
2. Implementing a 6 log (pasteurization) kill-step;
3. Proposal of a language change related to failing a state microbial test "that will allow for a process to pasteurize cannabis without changing its form in order to meet state testing level thresholds of 10,000 CFU/g." "This language change would accommodate for a pasteurization process, instead of immediately moving to extraction below the 100,000 CFU/g level."
4. Recommendation that language is included "that determines the spoilage criteria of cannabis" as "it is imperative to include TYMC and TAC as a quality indicator for cannabis in order to ensure consumer safety."

Mr. Hageseth's written comments, as well as a tobacco study he submitted that supports his position, is attached to this report as Exhibit 5.

Agency response:
While Total Yeast and Mold Count and Total Aerobic Count was considered it was determined after speaking with other states that this type of testing is only a presence absence test and are thought of as being antiquated quantitative methods. Many non-pathogenic and non-harmful microbes could cause a fail result if this testing were to be required. The agency has chosen to focus microbial testing on pathogens that are known to be harmful instead.

The OHA is unable to adopt rules around a 6 log kill step for producers. This is a rule that would need to be considered by the Oregon Liquor and Cannabis Commission since they regulate the production process. OHA only has authority to adopt rules around testing.

OHA agrees with the proposed recommendation of allowing marijuana and usable marijuana to be remediated without changing its form. The OHA will be modifying the proposed rules to allow for remediation through sterilization for marijuana and usable that fail microbiological testing. Sterilization is defined as the removal of all microorganisms and other pathogens from a marijuana item or industrial hemp-derived vapor item by treating it with approved chemicals, subjecting it to high heat or other process.

Usable marijuana going to retail sales will need to pass a water activity and moisture content test. This test will ensure that levels of water and moisture in usable marijuana are low enough to not allow the growth of organisms.

Dominik Skulec

Mr. Skulec wrote to express his dissatisfaction with the new rules, opining that they "hugely disadvantage small growers."

Mr. Skulec's written comments are attached to this report as Exhibit 6.

Agency response:
Thank you for your comments. Smaller growers were considered during the rule making process. During the rules advisory committee meeting the cost of the new tests was discussed. It was determined that through changes being made to the way items are sampled will help offset the cost. In addition, the timeframe for a harvest is being expanded from 72-hours to 7-calendar days to assist smaller growers in being able to submit larger batch sizes. A harvest lot of marijuana does not need to be strain specific and all tests, except testing for potency, may be composited across the different strains harvested within a seven-calendar day period. The addition of mycotoxins, heavy metals and microbiological contaminants will increase the public health and safety of cannabis items for consumers.

Hopeful Producer

A person who identified themself as "Hopeful Producer" wrote that they "agree the new definition of a harvest lot being expanded from 72 hours to a week will help small micro-tier producers save money and time. However, the expanded 50 pound batch size for testing will not help the producers that are so small that they cannot reach that limit on a single harvest lot."

Hopeful Producer's written comments are attached to this report as Exhibit 7.

Agency response:
Thank you for your comments. Smaller growers were considered during the rule making process. During the rules advisory committee meeting the cost of the new tests was discussed. It was determined that through changes being made to the way items are sampled will help offset the cost. In addition, the timeframe for

a harvest is being expanded from 72-hours to 7-calendar days to assist smaller growers in being able to submit larger batch sizes. A harvest lot of marijuana does not need to be strain specific and all tests, except testing for potency, may be composited across the different strains harvested within a seven-calendar day period. The addition of mycotoxins, heavy metals and microbiological contaminants will increase the public health and safety of cannabis items for consumers.

Jenilynn Monfrey, Limpy Creek Cannabis, LLC

Ms. Monfrey wrote that she "object[s] to adding these additional tests and requiring the labs to purchase several thousand dollars worth of new equipment, thereby having to raise the costs of full compliance test to the producers." She further opined that "this rule is unfair to any producer not able to have a 100 pound harvest…A producer that has a 3 to 15 pound harvest really cannot afford higher lab costs."

Ms. Monfrey's written comments are attached to this report as Exhibit 8.

Agency response:
Thank you for your comments. To clarify, the new proposed rule is for 50.0 pound batch sizes maximum, not 100 pounds.

Smaller growers were considered during the rule making process. During the rules advisory committee meeting the cost of the new tests was discussed. It was determined that through changes being made to the way items are sampled will help offset the cost. In addition, the timeframe for a harvest is being expanded from 72-hours to 7-calendar days to assist smaller growers in being able to submit larger batch sizes. A harvest lot of marijuana does not need to be strain specific and all tests, except testing for potency, may be composited across the different strains harvested within a seven-calendar day period. The addition of mycotoxins, heavy metals and microbiological contaminants will increase the public health and safety of cannabis items for consumers.

Laurie Andrade

Ms. Andrade wrote to "express [her] extreme concern for the lack of testing that will be taking place in regards to molds and mycotoxins in cannabis." Ms. Andrade's written comments address her concern about the high levels of mold

in cannabis and the lack of testing that is required for mold, citing her own study on shelved cannabis in February 2022 that showed high levels of mold counts.

Ms. Andrade opined that "Oregon should be at the forefront of consumer health and protection" and "consumer health and safety should be addressed with limits that have been thoroughly studied and already set by the FDA and USDA regarding mold counts in the food supply and pharmacopeia." She further opined that "the OHA should not be risking the public and human health without backing up their findings with Science based evidence that mold does not affect human health."

Ms. Andrade's written comments are attached to this report as Exhibit 9.

Agency response:
Thank you for your comments. While Total Yeast and Mold Count and Total Aerobic Count was considered it was determined after speaking with other states that this type of testing is only a presence absence test and are thought of as being antiquated quantitative methods. Many non-pathogenic and non-harmful microbes could cause a fail result if this testing were to be required. The agency has chosen to focus microbiological testing on pathogens that are known to be harmful.

Lp

A person who identified themself as Lp wrote with three main comments and opinions:

1. "We need some kind of state bank we can use for the tax money from cannabis sales to go; and also medical cannabis users need to be able to report costs of medical cannabis on state income taxes as a deduction along with other medical not reimbursed."
2. "Recreational and medical cannabis needs to be separated in different buildings or sections of buildings so that rising process for recreational doesn't automatically increase price of medical marijuana."
3. "Cannabis, both recreational and medical should be organic" and "need to not be treated with poisons to prevent the plants from infestations of mites or molds."

Lp's written comments are attached to this report as Exhibit 10.

Agency response:

Thank you for your comments, however they are not relevant to the rulemaking.

Milan Patel, Founder and CEO, PathogenDx

Mr. Patel wrote with a recommendation to "modify the new Aspergillus testing standards to remove the requirement for enrichment, as long as a testing method has been certified by an independent scientific body (such as the AOAC) and validated at an independent test lab to not require it, and the candidate Alternate DNA method shows equivalency to the reference method (plate culture) in terms of fractional recovery, and no statistically significant difference between the two methods."

Mr. Patel's written comments, attached to this report as Exhibit 11, provide specific suggested language changes to OAR 333-007-0390, Standards for Microbiological Contaminants Compliance Testing, related to his recommendation.

Agency response:
Thank you for your comments. OHA agrees with the proposed recommendation for alternate DNA-base testing methods for aspergillus testing if the method has been approved by a scientific body.

Naomi Carbone, Quality Manager, Sun God Medicinals

Ms. Carbone wrote that while "we appreciate and respect that OHA has identified issues and has taken action to further ensure the safety of cannabis and hemp consumers…we do not agree that these changes will have a limited financial impact; we believe that these changes will have an enormous financial impact to producers, processors, labs, and eventually to consumers." Ms. Carbone also wrote that "we understand and agree that additional testing is needed to ensure the safety of the products entering the market. We do not agree, however, that the elimination of Control Studies will further the cause of consumer safety."

Ms. Carbone provided an example using one of their current products to illustrate her comments regarding the elimination of Control Studies and the "extremely burdensome" fiscal impact that the new rules will have to her company. She wrote that "we strongly advocate to keep Control Studies as an acceptable sampling and testing method as there is insufficient evidence that Control Studies have a negative impact on the safety of consumers. If Control Studies

cannot be kept, we ask that current control studies be honored until their expiry date."

Ms. Carbone further wrote to "strongly disagree" that the financial impact of these rules will be minimal to producers and processors, opining that "sampling costs are not going to decrease with these rule changes because the laboratories are going to have to increase prices to pay for the equipment and accreditation to comply with these rules. These costs will be passed on to producers and processors as more samples are required, more labor, time and milage, and sampling fees are going to be required."

Ms. Carbone wrote to "advocate for clearer guidance regarding homogenization of samples," stating that "it is unclear in these rules as to where the homogenization should take place." She expressed that "as a seed-to-sale company, we need to know the methods that our laboratory partners adhere to, especially if we use more than one laboratory for testing."

Ms. Carbone's written comments are attached to this report as Exhibit 12.

Agency response:
Thank you for your comments. To clarify, an infused pre-roll will fall under the new category of finished inhalable cannabinoid product. If you make 1,000 infused pre-rolls each weighting one gram, then you end up with 1.0 kilograms of finished inhalable cannabinoid products. A 1.0-kilogram batch of finished inhalable cannabinoid product will be sampled and tested according to the new Table 7 under OAR 333-007-0360, Exhibit B. At a weight of 1.0 kilograms only a primary and duplicate sample will be taken and tested for pesticides, solvents (if required), potency, mycotoxins starting July 1, 2022, heavy metals starting March 1, 2023 and microbiological starting March 1, 2023.

Also, to clarify, homogenization of samples occurs at the laboratory and not in the field by the sampler. Rules around homogenization are being clarified under OAR 333-064-0100.

Robert Thomas, CSci, CChem, FRSC, Principal Consultant, Scientific Solutions

Mr. Thomas wrote that he "believe[s] the Oregon action limits for heavy metals and the way they are defined are inadequate." He opined that "based on compelling evidence in the open literature, you should be defining an expanded panel of elemental contaminants, which are toxicologically relevant to the

cultivation, extraction, processing, packaging and delivery of medicinal cannabinoids, based on their method of administration (oral, inhalation and transdermal).

Mr. Thomas's written comments provide a link to a white paper that he authored, which he states "will give you a much better understanding of the sources of elemental contaminants in the life cycle of medicinal and consumer cannabis products." In closing he wrote that "the cannabis industry is moving towards regulating an expanded panel of elemental contaminants as federal oversight will soon become a realty [*sic*]," and that he encourages the agency "to take this into consideration as you set the regulatory framework for regulating heavy metal contaminants in your state to ensure consumer safety."

Mr. Thomas's written comments are attached to this report as Exhibit 13.

Agency response:
Thank you for your comments. Adding additional heavy metals to be tested for in Oregon will be considered in a future rulemaking.

Rowshan Reordan, CEO and Founder, Green Leaf Lab

Ms. Reordan commented that the statement identifying how the adoption of the proposed rules will affect racial equity in Oregon was incomplete because it only looked at the impact to certain OLCC licensees and did not include impacts to testing laboratories. She also commented that the statement of fiscal and economic impact was incomplete because it "failed to adequately address and report the full description of reporting, recordkeeping, and administrative activities required to comply with the proposed rules" and "failed to include true cost of equipment, supplies, labor, and increased administration required to comply with the rule."

Ms. Reordan's written comments also request specific effective dates or a change to implementation dates for certain parts of the rules, noting that some of "the proposed rule[s] [lack] a specified implementation date." She opined that "not including a specified implementation date in the proposed rule[s] is unclear and is not transparent" and that it is "burdensome and creates a substantial hardship on small minority and women own laboratories" to require "rule changes that reduce laboratory revenue and increase laboratory costs without any specified time or insufficient time to implement." Her written comments also detail the steps involved in implementing the proposed changes, as well as the

specific impact to her laboratory and others as a result of the proposed changes in the following seven areas specifically:

- Repeal of OAR 333-007-0440, Control Study – request for October 1, 2022 effective date;
- Amendment of OAR 333-007-0360, Exhibit B, Table 7, Updated sampling increment requirements for extract/concentrate/inhalable product testing – request for October 1, 2022 effective date;
- Amendment of OAR 333-064-0100(2)(g), Cannabis Sampling Procedures and Testing (Sample replicate analysis) – request for October 1, 2022 effective date;
- Amendment of OAR 333-007-0350(1)(b), Batch Requirements for Compliance Testing (batch size increase from 15lbs to 50lbs) – request for change of effective date from July 1, 2022, to October 1, 2022;
- Amendment of OAR 333-007-0425, Standards for Mycotoxin Contaminants Compliance Testing (addition of new testing requirements) – request for change of effective date from July 1, 2022, to October 1, 2022;
- Amendment of OAR 333-007-0390, Standards for Microbiological Contaminants Compliance Testing (addition of new testing requirements) – request for change of effective date from January 1, 2023, to July 1, 2023;
- Amendment of OAR 333-007-0415, Standards for Heavy Metal Compliance Testing (addition of new testing requirements) – request for change of effective date from January 1, 2023, to July 1, 2023.

Ms. Reordan's written comments are attached to this report as Exhibit 14.

Agency response:
Thank you for your comments. In OAR 137-001-0060(2) it states in part that rules shall be effective upon filing with the Secretary of State unless a different effective date is required by statute or specified in rule. The rule you reference in your comment was OAR 137-003-0007. That rule refers to procedures for contested case hearings which a rulemaking does not fall under. OHA will be adopting rules upon filing with an implementation date of March 31, 2022. That will allow laboratories time to prepare for the rule changes.

The timeframe associated with implementation of the new tests were discussed during the RAC process and the laboratory representatives did not believe that the proposed timeframe would cause a burden. In addition, the financial impact

to laboratories was also discussed during the RAC process. It is a business decision for a laboratory to determine which tests they want to be accredited for and they are able to do so at any time. A laboratory is not required to become accredited for all tests.

The addition of the new tests has been discussed in two separate RACs and a workgroup over the course of a year and a half. A letter sent out on January 5, 2021, by ORELAP and posted on their website outlined areas of accreditation which included heavy metals, mycotoxins and microbiological in anticipation of these new tests coming on board.

OHA disagrees with the suggested effective date of October 1, 2022. This would create a greater hardship for many in the cannabis industry since it is in the middle of harvest season and could cause much more confusion and possible backlog in testing due to the increase of testing demand during this time. OHA would like to acknowledge that due to global events occurring that there could be delays in the supply chain and will be extending the date of when heavy metal and microbiological testing will come on board to March 1, 2023. It is important to not extend this date too far since these new tests do increase consumer protection.

It was determined through the RAC process that a replicate sample for solvents and potency was sufficient. This is a concept that originated from the workgroup held prior to the RAC and was brought forward by a testing laboratory as a recommendation to consider. This will catch pockets of solvents and ensure a more accurate potency result. Regulations already require representative sampling which should not result in a diluted sample for pesticides.

The rulemaking and planning of these rules included OMMP, ORELAP, OLCC and ODA. Their resources and duties were addressed in the rulemaking through their direct input.

Sam Tracy, Associate, VS Strategies

Mr. Tracy wrote that in reviewing the proposed changes to chapter 333, he noticed a drafting error that could cause issues for people trying to understand and comply with the rules.

He noted that "the error is that the word 'contaminate' (or 'contaminates') is sometimes used when 'contaminant' (or 'contaminants') is the proper word. 'Contaminate' is a verb, while 'contaminant' is a noun."

Mr. Tracy commented that "while these sound similar in speech, I worry that this error could cause problems for people reviewing the regulations – for example, if someone was trying to identify all of the provisions regarding contaminants by searching for 'contaminant' they could miss relevant items because the word 'contaminate' was accidentally used."

Mr. Tracy's written comments are attached to this report as Exhibit 15.

Agency response:
Thank you for your comment. The change of the use of “contaminate(s)” to “contaminant(s)” has been made in the proposed rules.

Sherman Hom, PhD, Director of Regulatory Affairs, Medicinal Genomics

Dr. Hom wrote to recommend a change to OAR 333-007-0390:
(3) Aspergillus speciation testing shall be performed using a qPCR analysis or alternate DNA-based method on sample material that has been enriched in a media that supports the growth of fungi for a minimum of 24 hours.

Regarding his recommended change, Dr. Hom wrote "AOAC certified qPCR methods have been validated using different cannabis sample types, such as flower, infused products, oils & concentrates, as well as industrial hemp, where a 24 hour enrichment was part of the sample processing before analysis with the qPCR assay."

Dr. Hom's written comments are attached to this report as Exhibit 16.

Agency response:
Thank you for your comments. OHA has modified rule language to allow for an aspergillus testing method that has been certified by an independent scientific body and removed the 48-hour requirement. The certified method will need to show equivalency in terms of fractional recovery with no statistically significant difference between the method and a reference method requirement enrichment such as plate culture.

Tyler Wolk, Co-Owner, Juniper Analytics

Mr. Wolk wrote to express his concern with the change to a 50lb batch size and how this change will impact his business as a lab owner, making it harder to find business and reducing the testing market. He also expressed frustration about the batch size already being raised previously, writing that "[labs] buy equipment based on how many tests we expect and when you change the rules and require less samples we can not make money."

Mr. Wolk also opined that metals should not be added to testing requirements because he doesn't "believe enough people will fail" and it will end up costing labs more in the long run.

Mr. Wolk's written comments are attached to this report as Exhibit 17.

Agency response:
Thank you for your comments. This is the first-time batch sizes have been changed in rule. A batch size of 50.0 pounds is the maximum allowable batch size. Smaller amount may be submitted for testing. Oregon is seeking to align testing rules with California and consulted with California on increasing the batch size to 50.0 pounds. It was indicated that the average size submitted for testing is closer to 25 pounds. Regulations already require representative sampling which should not result in a diluted sample. In addition, batches must be presented in 15-pound batch containers to ensure samplers have access to whole batch size being sampled.

EXHIBIT 1

From: Mitra Sticklen
To: Public Health Rules
Cc: Blake Rogers
Subject: Written comments regarding proposed permanent rulemaking – OAR chapter 333, divisions 7 and 64: "Marijuana and hemp testing and laboratory accreditation standards"
Date: Friday, February 18, 2022 11:36:39 AM

My name is Mitra Sticklen, cc'd is Blake Rogers, and we represent OM Extracts in Jackson County. We are an OLCC Processor and formerly an OMMP Processor that has served Oregonians Mindful Medicine since 2014. We operate in both the OLCC Marijuana and ODA Hemp space.

- **Our company supports the proposed added testing requirements for heavy metals, mycotoxins, and microbiological contaminants, on Marijuana items and industrial hemp-derived vapor items. We suggest including all Industrial Hemp items in these testing requirements.** Cannabis plants are a bioaccumulator of the many heavy metals in fertilizers, foliar sprays, irrigation water, wildfire smoke and even natural Oregon soils. Harvested hemp plants, not just hemp vapor items, are just as likely to contain heavy metals, mycotoxins, and microbiological contaminants and we believe Hemp consumers should be as protected from these toxins as Marijuana consumers.

- We fully support the change in sampling protocols and the expansion of harvest lot to 7-calendar days and up to 50lbs.

- We are in support of repealing the Control Studies rules. The Control Studies cost has created a financial barrier for our family-owned company to launch new, safely tested, consistent Extracts. The proposed update will continue to ensure consumer safety while reducing the financial burden for producers, processors, retailers and ultimately consumers.

- **Our company proposes a reduction in the maximum ethanol (Residual Solvent) limit for Marijuana Extracts from the current allowable limit to 1,000ppm to enhance customer safety.** This is especially important for inhalable Marijuana Extracts, but even for extracts that are eaten or used in suppository, the currently allowed large quantities of ethanol can be very harmful for mucous membranes. Since Oregon doesn't currently differentiate between extracts meant for inhalation and other extracts, we advocate requiring a limit that is low enough to be safe for even inhaled extracts. For example, California set the maximum allowable Ethanol limit for inhalable goods at 1,000ppm. We advocate amending OAR **333-007-0410,** to update the maximum allowable Ethanol limit for Cannabis Extracts and Concentrates to 1,000ppm.

- **We advocate adding a test for sulfur to the Pesticides testing list and establishing an allowable maximum limit for Sulfur compounds.** Although Sulfur is a basic compound that plants use to grow, Sulfur is also one of the most commonly used treatments for mites, even during the flowering phase in some farms. Burning excessive sulfur residue creates sulfur dioxide, which is a known toxin when inhaled. We urge the OHA to look into this issue and establish a reasonable and safe maximum allowable limit of Sulfur as a pesticide.

Thank you for the opportunity to comment. Although we represent a for-profit company, our primary focus is Patient and Customer Safety and Health above all else. Please let us know if there are further opportunities to serve Oregon consumers, OHA, OLCC and ODA as the rules continue to evolve.

Mitra Sticklen
Central Operations Officer
Cultivation & Education
541-654-1007
www.omextracts.com
Find us on Instagram, Leafly, and Weedmaps

EXHIBIT 2

From: Jamie Toth
To: Public Health Rules
Subject: Written Comment
Date: Monday, February 21, 2022 1:14:59 PM

In addition to my oral comment, I just wanted to add the following.

The Corruption of Trust in Oregon's Cannabis Labs

Without action, public and industry trust in cannabis laboratories will continue to erode.

I enjoy writing about cannabis science because it's an exciting time for cannabis. I like helping other people to understand what they are seeking from their cannabis experience — and figuring out how to get it. I try to process what science has to say about how cannabis impacts us and demystify it to make it more understandable for people seeking its benefits.

When I first started exploring the story about laboratories in Oregon in 2019, I thought that the story was whether there are some rogue labs in Oregon. Someone in the industry advised me to stop writing about it. If I was a journalist, that would have told me that not only did I have a story, but I had a good one.

I'm not a journalist.

Two years later when I heard people in the industry say that it was still an issue, I decided that not only was there was a story,- I wanted to know what it was. To chase down that story, I pulled the list of labs across Oregon and planned out a round robin by calling every lab on the list. It was an extraordinary and humbling experience — there are a vast number of dedicated scientists who want to produce the best number possible. I talked with people who have a deep abiding love of science and cannabis and want to do best by them both. They are inspirational people whose work is threatened by the power of strong economic forces.

In some cases, they reached out to me from to not only tell me that they suspected their lab was fixing results, but how. Some laboratories shared emails where they had retested samples from shelves, and sent the tests to the state. Still others offered advice on pertinent studies.

Hearing their stories and fears and getting their advice about how to proceed made me understand quite a bit more about the cannabis industry in general, in addition to the limits and challenges of those working in cannabis science.

It was their advice I used to help formulate the round robin plan.

But the biggest issue? Funding.

I couldn't crowdsource — I would be using part of the funds to acquire samples and purchase cannabis-related services. Since cannabis is federally illegal, collecting money with the intent to buy it is also federally illegal. I moved to a legal state and became a medical patient to avoid breaking laws.

The only legal way to move forward with the round robin was with funding from within the industry itself. To perform a true blind test would require being able to front all of the lab fees — over $10,000. Then, the pure logistics of trying to get samples, homogenize them, and get them to the labs — all without the labs knowing it was related to my 'blind' experiment?

It was too much financially and logistically for a writer to bear. Honestly, it's also outside of my scope — If

someone wanted to discredit the work, all they would have to do is discredit me. I don't have scientific training, or letters after my name. As someone told me — I wouldn't be the first to try it and I wouldn't be the last.

When I talked with my State Representative, John Lively, about funding issues and logistic issues, he advised me that the only legal way forward for me was funding from within the cannabis industry.

The only people interested in funding? Cannabis labs whose business was under threat. Which meant I had to ask the labs to trust each other.

Spoiler Alert: In many cases, they don't.

While I had initial consensus from the labs, once one stepped up to the forefront to help, interest in the project evaporated because the conflict of interest was clear.

There will still be a round robin, but on a smaller scale. The results will still be relevant, but still dismiss-able by those who won't like the results.

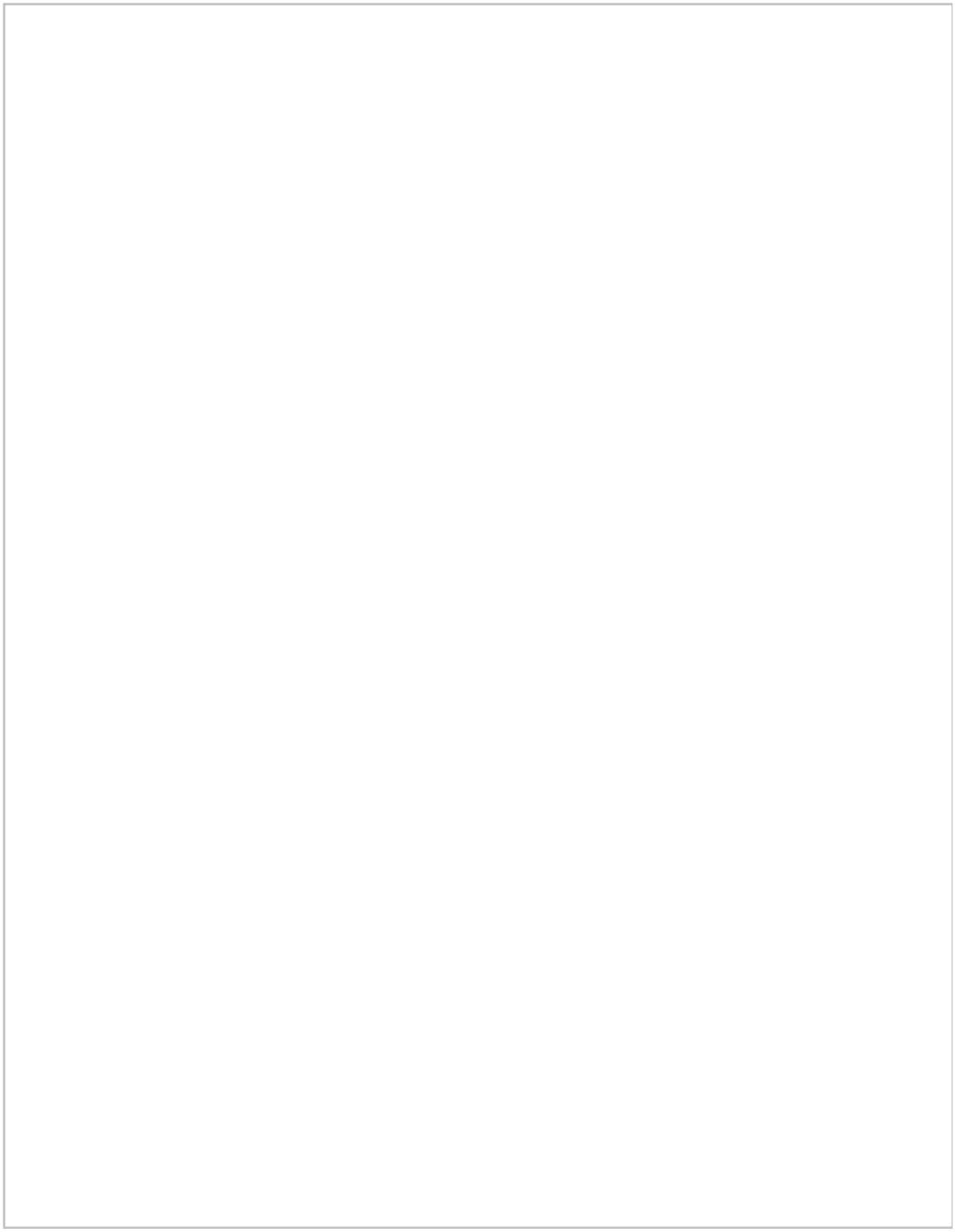
What the Data said . . . and What it Couldn't.

As a data architect, more of my hopes hinged on the public records request. I performed an analysis of the 250,000 records for THC tests that the state of Oregon keeps in its Cannabis Tracking System. I quickly received four years of de-identified data in quick time, and I'm grateful to TJ Sheehy and his team who made that happen.

The records request showed not only issues with the labs, but also issues with data collection and governance (those are always to be expected in data sets like this). But even though it was a perfectly formatted imperfect data file, it still had a lot of relevant information and told quite a story.

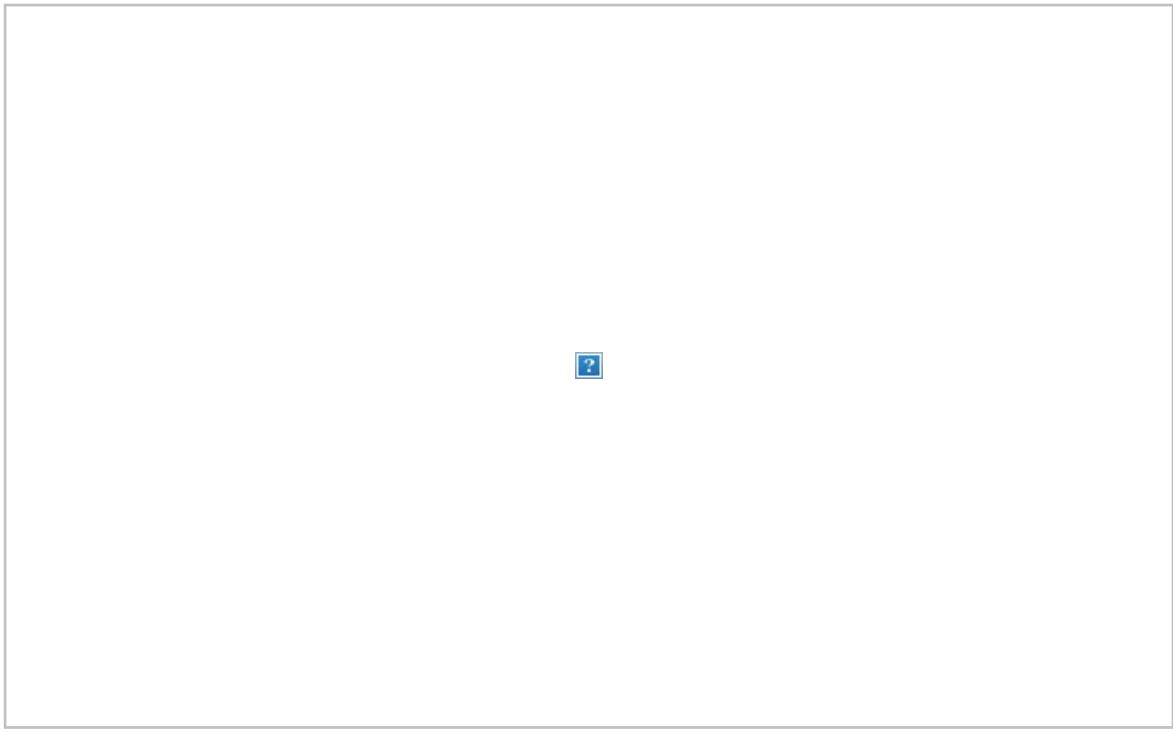
In a prior story, I wrote about research into issues with labs in Washington and Nevada. That research gave evidence that there were issues in the labs by examining a frequency analysis and noting the 'bump' that occurs around 20% THC, which is a significant number for marketing.

Here are the graphs from the Washington and Nevada Study.

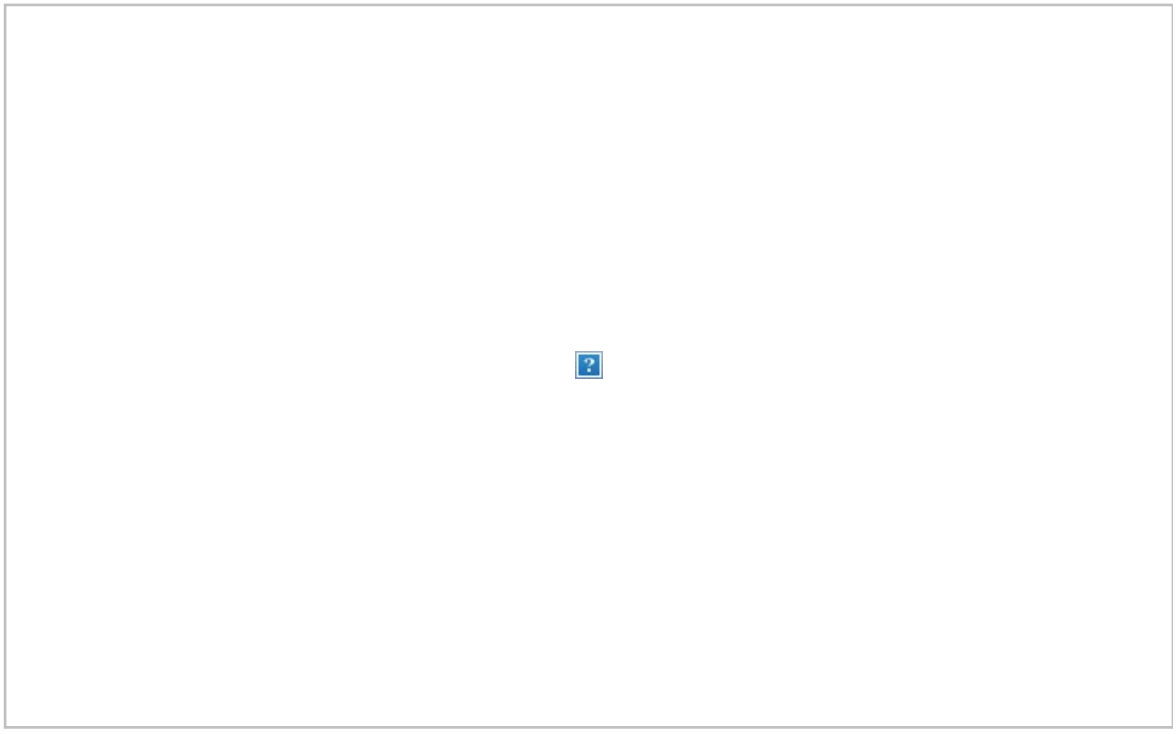


Using my 20 year background in health care data analytics (I'm even published!), I performed the same graphing on Oregon's test results. Unlike other areas — I have expertise in this one.

Here is a graph of Oregon's 2021 THC Potency Results for product entered as 'Buds' in METRC.



Here is that same data set, with three labs eliminated. How did I pick the labs? By looking for labs that had abnormal behavior compared to the above curve.



I understand why people would say ‘that doesn’t really say anything.’

To me it says a lot.

I heard how many thought that perhaps cannabis results wouldn’t conform to a normal curve — and yet — with just three labs eliminated, the curve has started to look far more normal. It doesn’t peak at 20, nor should it — the average THC concentration in Oregon is actually at 23.3 for the year of 2021. Which is exactly where this data set peaks.

Isn’t data neat?

What’s the Story, Morning Glory?

Once I allowed myself to step back a moment, I was able to see deeper so I could process what I had experienced.

Scores of phone calls reinforced that many in the cannabis industry believe that some rogue labs are fixing the THC results . These people are often so certain that they will name names — and claim the state is unable or unwilling to deal with the problem. Despite the fact that many in the industry believe there are rogue labs, they still engage with them. Farmers still get their cannabis tested there to reap the economic benefits. Dispensaries still stock product tested by them, while admitting they don’t believe the posted numbers. Labs still subcontract for them.

I thought this was a story about whether there are ‘bad actor’ among cannabis laboratories in Oregon, but I was wrong.

This is a story about the how there is an industry-wide erosion in trust in the ability of cannabis labs to deliver accurate scientific results in the face of extreme economic pressure.

Ever the stickler, I wanted undeniable proof.

The issue is — if someone’s job hinges on not believing you, it doesn’t matter what proof you bring to the table. I was even told as much. For those people — no proof someone like me could provide would ever be good enough. For those people, nothing is undeniable.

The Open Secret.

This is the part that hurts the most for a variety of reasons, but I’ll stick to the less personal ones (and even those are personal).

I’ve spent so much time evangelizing that consumers need to check lab reports and lab information that it hurts to find out there’s such a serious issue. It’s disheartening to know how many budtenders, shop owners, farmers, wholesalers, and yes, lab technicians — that know this is going on. What’s worse is seeing how little the cannabis industry has tried to educate the consumer to try and take the pressure off of the labs.

The ‘open secret’ situation around some rogue Oregon labs fixing THC potency is a textbook example of corruption. An authority (laboratory) manipulating results to their economic benefit — right out in the open.

Open secrets aren’t well-kept. All you have to do to be in on this one is call up a dispensary with a high tester with a ridiculous low price — and ask them who tested it. Everyone will tell you about it, but no one will want you to print their name.

I’ve heard it said that the standard you walk past is the standard that you accept. Applied to this situation, it’s clear that regardless of their willingness to talk about their suspicions, many in the industry are fine with the status quo.

Don’t believe me? Look at who offers consumer education and who doesn’t. You can determine what companies value by what they spend resources on.

All you have to do with this is follow the money.

Some labs, when feeling defensive, asked me what *I* was doing to ensure people were being educated about cannabis. One ranted at me for over two and a half hours about how my idea was stupid, and I was an idiot for pursuing it. Another told me that writing about the cannabis lab issue in Oregon was not only a waste of time but would ‘ruin me.’ They continued to tell me how better people had done the story (referring to a piece in a local paper) and had been ‘shut down.’

But that’s not where the accusations stopped.

‘It’s the Consumer’s Fault!’

The number one comment I heard from people across the industry is that it’s the consumer’s fault. It’s the consumers seeking THC, it’s the only thing they want, it’s the only way they order. According to some industry experts, the entire situation is due to the ignorance of the consumer.

It doesn’t take much research to see which cannabis brands have invested in consumer education. An easy way to find which dispensaries, farms, and labs invest in consumer education is by a simple web search. After COVID-19 there’s no longer an excuse for cannabis brands to eschew the internet. It’s surprising how few have established websites, engage with consumers about their services and credentials, or give material and links to valid research stated in simple terms.

The industry that claims it dangles on a precipice because of consumer ignorance hasn’t made major strides in educating consumers.

Letter of the (Labeling) Law

It’s true that many might not understand the impact of what the labeling rules actually say. It’s easy to admit that the accusation that it’s the consumer’s inability to understand what the label is telling them might have some validity. It’s also easy to see that the misconceptions of what cannabis labels say can’t cover the scope of the issue.

Redacted Oregon Cannabis Flower Label. Image Source: Author

One of the big points made in the General Requirements section is that “Packages cannot contain untruthful or misleading statements.” As someone who used to work in a field full of stringent regulatory requirements (healthcare), I read that to be a blanket statement, so that if ***any*** statement on the label is willfully falsified, that it’s an actionable infraction.

There’s also a delightful nuance in that the rules that states the THC and CBD for usable marijuana as dry weight — but this doesn’t mean just a bit dry. This means cracker dry — drier than you’d ever want to buy it. That means that the THC on the label will seem slightly higher than it should be, because the cannabis inside (hopefully) still has a bit of moisture (less than 15%).

Let’s talk about the star of the show and the center of this drama: THC.

The most important thing to understand is that what you’re seeing on a label for “THC” is, even in the best of cases, an estimate. Even if the number on the label was 100% accurate, the lab can’t have actually tested the bud you’re about to enjoy. Part of how labs derive that number is by using sampling techniques performed on batches of material. ORELAP accredits the sampling technique of each lab, and lab personnel must follow those documented and accredited procedures. Currently those batches are 15 pounds, but there is talk of increasing the batch size to 50 pounds.

I don’t have confidence that increasing the batch size of 50 pounds is in the interest of consumers. In a batch of 50 pounds, it’s rather meaningless, unless the Relative Standard Deviation, a statistical metric that describes how much variance there is in results, was required in addition to THC.

To complicate matters more, the rules for labeling state that the THC number reported should be the potency at the time of consumption — not at the time of testing.

Don’t have enough complication yet? The potency only expected to be within 20% of the value on the label. This means it’s acceptable, by law, that an 18% cannabis carry a label for 21% and be considered accurate. That doesn’t seem like much, but there are large economic incentives noted in the market for cannabis that is over 20%.

But if you bought something that said it was 91 octane, and it was 87 — would you be angry? Would you trust the vendor again?

There Ought to Be a Law

Cannabis Laboratories in Oregon are licensed by the OLCC but have their processes, procedures, and equipment accredited by ORELAP. When I wrote to the state about my concerns around cannabis potency testing, Jonathan Modie, Lead Communications Officer, explained, “The rules around testing potency on cannabis try to address the issues you have raised. The OMMP, which resides in Oregon Health Authority, has the authority for setting testing rules for cannabis. The Oregon Environmental Laboratory Accreditation Program (ORELAP), also in OHA, has the authority to oversee testing laboratories and accredit them to national standards that are based on ISO standards but specifically tailored to environmental testing laboratories. Oregon does not have a reference lab which would be able to test products and act as independent third party to assure results from labs are accurate.”

Unfortunately, many laboratories believe that these national standards fall short in giving guidance and standards criteria appropriate and specific to cannabis, and without an established reference laboratory or reference mechanism, there’s no consistent way for the state to ensure consistency in testing across the laboratories.

Viruses and Water Wars

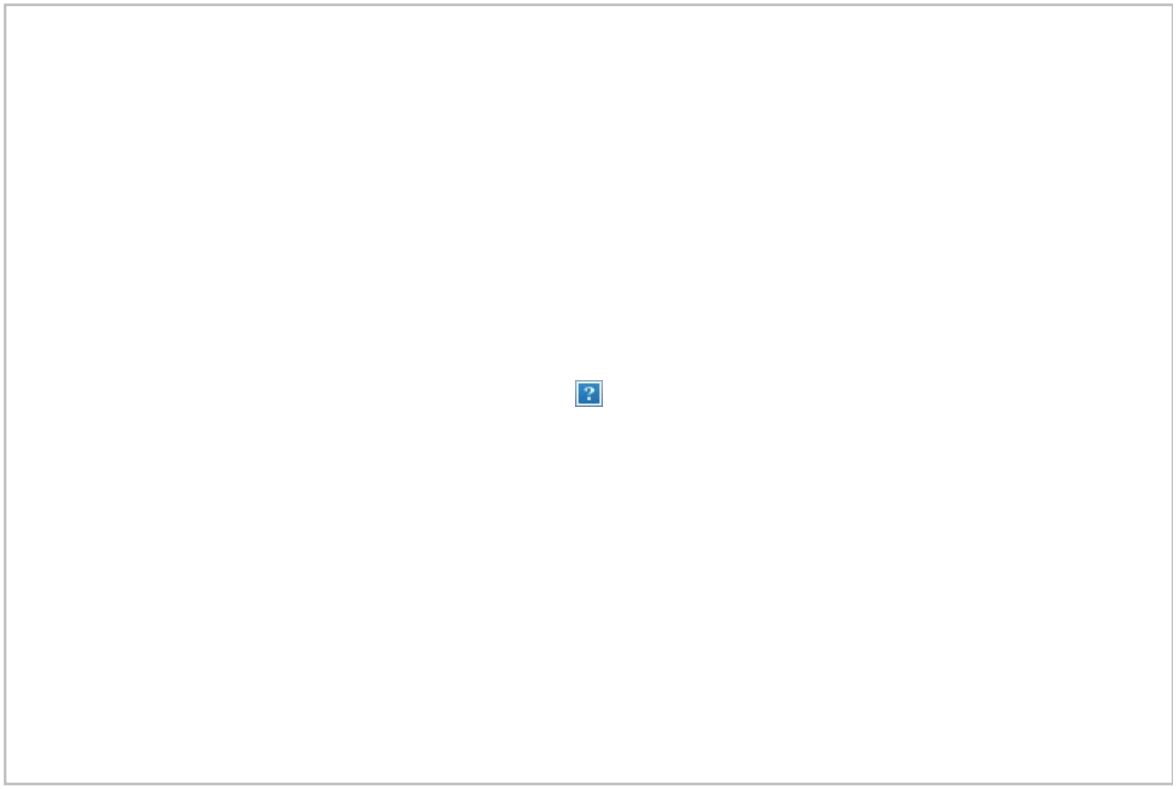


Photo by everett mcintire on Unsplash

Modie's email went on to explain, "ORELAP performs site visits to laboratories to ensure they are performing their testing according to set standards. Cannabis testing laboratories must go through a round of blind third-party proficiency testing for potency every 6 months to ensure they are utilizing methods that produce accurate results. If a laboratory does not maintain a record of acceptable performance in at least two out of the past three proficiency tests, the laboratory's accreditation is suspended for that testing. A laboratory's suspension is lifted when they can show acceptable performance."

I had already heard from laboratories that there had been gaps in the onsite audits due to the logistic complications brought on by the pandemic. Many labs also pointed out flaws in the six month proficiency testing system that could be exploited if a lab was a 'bad actor.' Some of these flaws included how easy it was to identify the samples for proficiency testing.

A raging pandemic that is changing how the state is able to audit isn't the only thing that is on Oregon's plate. Since the legalization of industrial hemp t here have been serious issues in Southern Oregon around illegal grows, especially on land that had once grown hemp, before the market bottomed out . News reports now include stories about massive drug busts, murders, and police who feel outmanned. Residents live in fear — not just of armed men in unmarked pick up trucks full of cannabis speeding down the roads, but of creeks run dry far earlier than usual, and run off from the farms polluting their streams and creeks.

Regardless of their growing war chest of licensing fees and tax revenues, all of this is a strain on OLCC's finite resources.

There is a public comment hearing on the 16 of February to review new proposed testing rules , and I've asked to share what I've found over the course of my adventure. Reviewing the proposed expansion of rules, I am still concerned that they are not sufficient to protect from some of the issues I've outlined here — and I don't see any specifics calling out mining the data available in the CTS to support audit efforts.

But the fact of the matter is — I'm a writer.

The stories I have to tell about cannabis lab testing are other people's stories.

The people who should be speaking at this hearing are the dispensaries, laboratories, and farmers who have not only expressed their sense of damage that the situation has done to their business to me, but the ideas they have to fix it.

As in most things, people have far more complaints than solutions.

What Can Be Done — and Who Would Do It?

It's an overwhelming amount of information, I know, but the most important thing to think about is how can a situation like this be changed — before trust is completed eroded and honest laboratories go bankrupt?

Oregon could increase data stewardship efforts so they could use METRC data more effectively

It was evident from looking at the data that there were issues. There were lab results that were far too high for flower (I can't imagine an 88% flower), and others that were far too low for concentrates. It's understandable that full data checks could not be performed in METRC's front end. A strong data governance effort that focused on stewardship at the laboratories that included reports to highlight issues would increase data accuracy within METRC.

Some of the pushback I received when I originally vetted the information I had gleaned from the data set that was METRC was the concept of garbage in, garbage out — and data governance projects would be an effective way to address those concerns. Since METRC requires coordination of data entry rules across the state and across organizations, without comprehensive training with centralized messaging and monitoring, the data will continue

to be troubled.

Oregon Could Change Flower Labeling Rules to Include More Available Information

The rule could be changed to include the RSD in addition to the THC — especially as the new rules acknowledge its importance to understanding how homogenous a sample is. Instead of emphasizing THC at time of consumption, it could emphasize THCA at time of testing. It could include terpenes. There are a lot of ways the state could disrupt the fixation on THC by adjusting cannabis labeling.

The Labs Could Create an Organization to Self-Regulate

I actually thought that this was pretty likely, but now I'm skeptical. It's a graceful-seeming solution: a laboratory coalition could pool resources to run regular lab round-robin events, make self-governing rules regarding standards that go above and beyond the state minimums, and help to educate consumers and market the coalition itself. Much like the American Medical Association sets standards for doctors, such an organization could establish standard advise the OLCC on market trends in addition to creating internal standards around sampling, calibration, and other topics that regulatory bodies such as the OLCC and ORELAP are unable to realistically create and maintain in such a quickly evolving environment.

The reason I'm not sure if it's likely is that I don't think that many of the laboratories feel threatened enough to require them take any definitive steps towards working with other labs that they see as direct competition. Without extraordinary amounts of pressure to overcome their distrust in each other, these efforts are likely to fail.

The Cannabis Industry and OLCC Could Increase Consumer Education

It's easier to find misinformation or overstated benefits of cannabis than good cannabis education. The industry itself could invest in programs to increase consumer education around cannabis. The industry could help consumers understand the importance of terpenes, cannabinoids, VSCs, and other compounds to the cannabis experience. They could give educational webinars on how growing methods impact the cannabis produced, and display information on studies regarding the impact of THC to the cannabis experience.

The OLCC could also invest in consumer education. Their materials They could invest in Point of Sale materials that explain exactly what that THC number actually means. The information I gathered for this article took scouring their website and administrative rules — and making this information as easily accessible as the OLCC's instagram page might give consumers the insight into THC that they need to make appropriate purchasing decisions.

State-established Rules Could Designate or Establish a Reference Lab — Even a Rotating One.

One of the biggest flaws identified in the 2019 audit of Oregon's Cannabis labs was the lack of a reference lab. The state could create a reference lab, designate current laboratory to serve as the reference laboratory for cannabis laboratories, or could designate a cannabis lab to serve as the reference lab on a rotating basis.

A reference laboratory is a laboratory that serves as a check on test results, helps set standards, review procedures. It can also help train laboratory staff, create certification standards, and assist in the standardization of laboratory data across the state via reference libraries.

Consumers Can Exert Pressure

As consumers, we don't have a lot of power in this situation, but there are some key things we can do. We can educate ourselves about what the labels tell us, and what we are seeking from our cannabis experiences so that we no longer order cannabis by the THC amount. We can ask for more information about our cannabis when purchasing, including lab that tested the product, terpene profiles, RSD, and other information to demonstrate interest in metrics other than THC. We can even go so far as to decline to purchase from brands that use particular labs or do not share enough information. While we have limited resources and recourse, we can change our buying habits.

Without meaningful regulation that includes appropriate audits and efficient controls, honest laboratories will be left unprotected in a market driven solely by escalating demand for inflated THC numbers and fraught with rogue actors. Without action, public and industry trust in cannabis laboratories will continue to erode.

Thank you for your time and attention,

jamie

EXHIBIT 3

Comments on Proposed Changes to Chapter 333

Marijuana and hemp testing and laboratory accreditation standards
Oregon Medical Marijuana Program

Submitted by:
Jill Ellsworth, Founder & CEO
On behalf of Willow Industries, Inc.

Thank you for the opportunity to comment on these proposed changes to Oregon's marijuana and hemp testing and laboratory accreditation standards. We appreciate all of the work that OMMP and ORELAP have put into this, from workgroups in 2021, to this notice of proposed rulemaking. The rules have become much stronger throughout the process, and we believe that only one small change is needed to ensure that the new testing requirements are workable.

Willow Industries works with cannabis cultivators and processors across the country, with a focus on decontaminating cannabis to remove harmful microbes using ozone. We strongly support the proposed regulations' mandatory testing for microbiological contaminants such as Aspergillus, Salmonella, and STEC, as high levels of these impurities can cause serious health problems to people who consume them.

We are also happy to see that the regulations include a modification to the definition of "sterilization" that includes chemicals, heat, or other processes. However, the section on Failed Microbiological Contaminant Testing only contemplates sterilization using processes that convert usable marijuana into a cannabinoid concentrate or extract. **Since there are multiple processes that can sterilize marijuana without changing its form, we respectfully request this language be changed to allow either type of process in response to a failed test.**

Recommendations:

1. Update 333-007-0450: Failed Test Samples to allow marijuana that has failed microbiological contaminant testing to be sterilized using methods that do not alter its form.

Suggested language:

We suggest modifying 333-007-0450: Failed Test Samples, as follows:

(6) Failed microbiological contaminant testing.

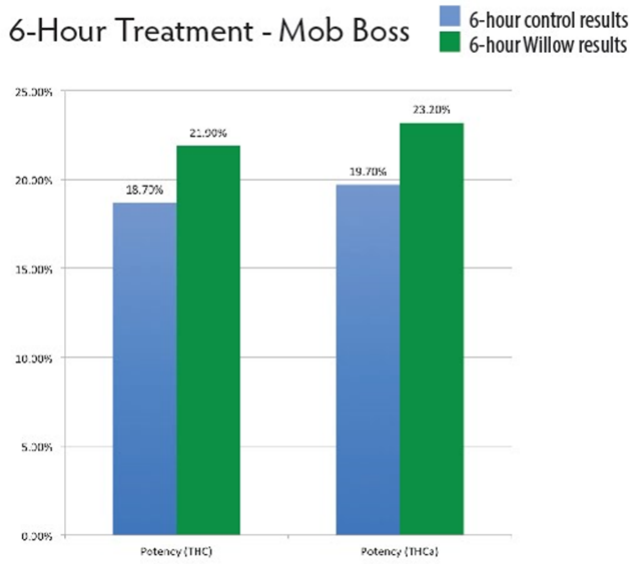
(a) If a sample from a batch of marijuana or usable marijuana fails microbiological contaminant testing**,** the batch may be **sterilized using a method that does not change its form, such as ozone. It may also be** used to make a cannabinoid

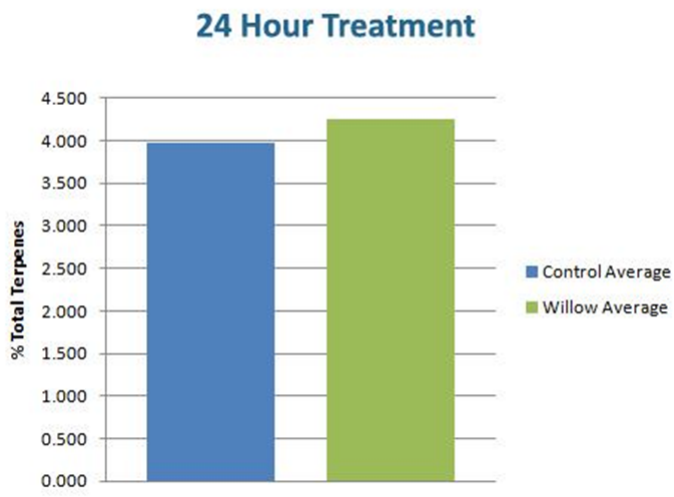
concentrate or extract if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon based solvent or a CO2 closed loop system.

Reasoning:

It is true that many extraction methods, such as those using a hydrocarbon based solvent or a CO2 closed loop system, can effectively sterilize marijuana that has failed microbiological contaminant testing. However, there are also many methods of sterilization that do not involve extraction, and instead leave usable marijuana in its current form.

For example, our WillowPure system uses ozone to kill microbiological contaminants on usable marijuana, while keeping its physical form intact. This process also does not disrupt the medicinal properties of the plant. For example, studies have demonstrated that treatment with ozone does not reduce either the potency or the terpene content of usable marijuana:





While sterilizing failed batches of marijuana via extraction is certainly preferable to destroying them, many operators would prefer to keep them in the form of usable marijuana. High-quality usable marijuana typically has a better sale price than extracted products, so being forced to convert it into a concentrate could lead to unnecessary economic losses. Additionally, even if pricing is comparable, many operators prefer the flexibility to respond to patient demand for various product types.

Changing 333-007-0450: Failed Test Samples as suggested above would ensure that operators can use processes like ozone to sterilize usable marijuana that fails these new microbiological tests. This will lead to better economic outcomes for Oregon patients and businesses, while protecting public health and smoothing the rollout of these new regulations.

Conclusion:

Thank you again for your consideration of our suggestions. Please do not hesitate to contact us if you have any questions or would like more information — we would be happy to provide any additional data that would be helpful as you consider these important issues.

Submitted by,

Jill Ellsworth
Founder & CEO
Willow Industries
jill@willowindustries.com

EXHIBIT 4

From: Alex Hoggan
To: Public Health Rules
Subject: Comments on Proposed Testing on Cannabis.
Date: Friday, February 4, 2022 3:29:51 PM

Hi my name is Alex Hoggan I am the owner of Chemhistory a cannabis testing lab. We have been in business for 8 years in Oregon. Feedback on the proposed rules.

With the idea that we don't have any data to support these new tests I would caution not to overtest. What I would suggest is that if a producer tests their plant material for Mycotoxins and Heavy metals that when it goes to processing they would only need 1 test to check for each of those analytes. If there was a positive hit then a confirmation test would be required. If a producer does not have the plant material tested and goes straight to processing then a prime and field duplicate would be required. This would very much help the over testing of products and keep the costs down. The instrument needed for mycotoxins is the same as pesticides; a LC MSMS refurb price is around $350,000.00, and with the run time only able to test around 100 samples per day. Heavy metal instrument $250,000.00 with a runtime could do 200 plus tests per day. With prime and dupe for concentrates it may require labs to get multiple additional instruments to meet this demand. That's my two cents. Having said that Chemhistory is ready for the new testing. Thanks Alex

Alex Hoggan
Director of Business Operations
5691 SE International Way B Milwaukie OR, 97222
T: 503.305.5252 | M: 801-809-2887
E: Alex@ChemHistory.com | W: www.ChemHistory.com

VIST

OHA, Public Health Division
Administrative Rules Coordinator
800 NE Oregon Street, Suite 930
Portland, OR 97232

EXHIBIT 5

Public Comment on Oregon's Proposed Rulemaking for Cannabis Testing: Microbial Testing for Quality and Consumer Safety

To Whom It May Concern:

My name is Christian Hageseth and I am a veteran of legal cannabis in the United States and Internationally. I have strong opinions on this matter based upon my professional experience, personal experience and what I know as "the industry's dirty secret". I started growing legal cannabis in Colorado in 2009. By 2012, I was also operating 5 dispensaries and my grows kept getting bigger, the latest is over 100,000 square feet. During this time, I have witnessed a young industry trying to figure out exactly who it will be in the end. I am the Author of "Big Weed", published in 2015, and have won 6 cannabis cups and was named one of the top dispensaries of the year by High Times magazine. I share all of this with you to establish my experience and expertise in the industry. The Cannabis industry's dirty secret is this: most participants in the industry are trying to "Get by - not Comply". Compliance often requires someone to validate that compliance, and the participants have found many ways around complying.

The lack of compliance is affecting our customers' health and safety. Please consider the points below carefully. It wasn't real to me until I got sick from smoking cannabis contaminated with aerobic bacteria and mold. The revised rules are leaving out a large majority of contaminants that will slip through the cracks and get more people sick. I implore you to consider the following facts and amend the recommended rules.

Today, I am a founder of VIST Labs, a cannabis decontamination and packaging company. We've invented a natural 6 log kill step technology to kill microbes in cannabis to below the threshold of 10,000 CFU/g. Expanding on 35+ years of experience in food, pharmaceutical and medical packaging, VIST systems provide both a purification step to kill microbials, as well as an aseptic modified atmosphere packaging step to protect cannabis from recontamination and prevent further microbial growth or potency degradation due to oxidation. This system ensures that when consumers open the product at retail level, growth of yeast, mold, and aerobic bacteria have been kept in check, as well as the potency profile and quality remains the same from when it was first tested. VIST's goal is to protect consumers and ensure their health and safety.

Background

The only way to know the true quality history for a given lot of cannabis flower is to follow strict sampling protocols and perform total yeast and mold counts (TYMC) and total aerobic bacteria

counts (TAC) using scientifically validated test methods. Many US states and Canada have adopted a 10,000 colony forming unit threshold per gram of cannabis. Used in microbiology, colony forming units per gram (CFU/g) refer to the estimated number of viable yeast, mold or bacteria in a given sample that is present on the cannabis. This can be enumerated to the number of living yeast and mold populations on cannabis and negatively correlates to the quality and safety of the product. The higher the number, the higher the contamination level, and the more mold or bacteria spores that will pass through the smoke and microcolonize in consumers' mouths, airways, and lungs.

Throughout the cannabis production and distribution process, microbial contamination can occur at any point: Grow, Harvest, Storage, Process, Transport, Retail. Moisture and oxygen in any environment can foster the growth of mold, yeast, and bacteria. Cannabis is a highly susceptible agricultural product, and the reality is that about 15% of cannabis fails the 10,000 CFU/g limit shortly after harvest. That failure rate continues to increase as the cannabis moves through the distribution process. The average growth rate of microbes has been documented to be over 20% per week, especially if the cannabis had not been packaged in a low oxygen environment.

The Food and Drug Administration (FDA), the Federal Trade Commission (FTC) and United States Department of Agriculture (USDA) have established maximum 100,000 CFU/g thresholds for various food and pharmaceutical products where total plate counts above that number means the product is "not fit for human consumption". The maximum allowable level of contamination for products like raw milk, raw meat, raw poultry, raw fish, and vegetables is 100,000 CFU/g and requires pasteurization to bring these food products to 10,000 CFU/g levels before human consumption. These spoilage limits and definitions protect the integrity and safety of the food and drug supply in order to ensure consumer health and safety and have led to one of the safest food and drug supply in the world.

Upon federal legalization of cannabis, it is likely that the FDA, FTC, and USDA will impose the same rules and labeling laws that are in place for food, medical, and pharmaceutical products including end of shelf life labeling requirements and truth in product claims for cannabis. Currently, all food and pharmaceutical products that exist on the market in the US are regulated under the FTC and have labeling laws, such as end of shelf life potency claims, ingredient lists, accurate expiration dates, and spoilage definitions. All label claims and declarations must be true at the end of shelf life. For example, if a cannabis product is labeled as having a 15% potency THC, this must be true until its expiration date listed on the label. If the potency has changed plus or minus a certain percentage, then it fails the labeling requirements and should be recalled. Many cannabis products that exist on the shelves today are failing these labeling requirements because the potency decreases over time due to oxidative factors. It is likely that cannabis products not packaged in a low oxygen atmosphere will have a much shorter shelf life due to the growth rate of mold and bacteria oxidation of cannabinoids. The FDA and FTC will require

accuracy of data and claims that are labeled on packaging and it must be true at the end of shelf life.

The Health Risk to Consumers

The danger to consumers and patients from inhaling microbially contaminated cannabis and tobacco is prevalent and can be seen in 50 years of tobacco data. Smoking heavily contaminated cannabis with high yeast, mold, and bacteria counts delivers hundreds to thousands of active spores into the mouth, throat, and lungs which colonize and grow in airways causing chronic infections and inflammation, threatening overall health and safety. These mold and bacteria contaminants present minor to severe respiratory infections, chronic lung disease, asthma attacks, severe allergic reactions, cancer, and microbial colonization of the mouth, throat, airway, and lungs.

One study proved the ease of live microorganisms being distributed via smoke into the mouth, airways, and lungs from tobacco and how it applies to cannabis. The study tested smoke from a single cigarette of tobacco (less than 20,000 CFU/g) and found it delivered hundreds to thousands of activated viable mold and bacterial spores to the airways of the user. They repeated the tests for a statistical population and the data revealed that about 1% or more of the initial microbial load in the product passes through the smoke alive and found it capable of creating infection to the user. It is not unusual to see mold or bacteria in contaminated cannabis facilities or grows with various plant diseases such as Botrytis (bud rot) and black or white mold, however, the facilities are likely testing at over one million CFU/g for mold or bacteria. At a 1% smoke pass through rate, a single joint would deliver 10,000 viable spores transported through smoke that is inhaled deep into the lungs. As yeast, mold, and bacteria are chronically inhaled, they then colonize in the respiratory tract of consumers, causing numerous ill health effects including chronic lung inflammation which is associated with malignant transformation and tumor growth. Oregon's proposed change to microbial testing for "pathogens only" would not fully protect cannabis consumers from the everyday reality of highly contaminated cannabis.

Another study demonstrated the relation between smoke and fungi/mold and the effects it had on mice. The investigators exposed mice to smoke from fungi/mold contaminated hay and found that the mice developed pulmonary emphysema and other pathological conditions. The control group, mice exposed to smoke from sterile hay, remained normal clinically. The study determined that the fungal/mold contamination caused chronic lung conditions in the mice and has been further linked in humans.

In addition to chronic health issues, the presence of high levels of bacteria and mold in cannabis dramatically affects the organoleptic properties of cannabis. These changes begin to occur as the TYMC and AC grow above 10,000 CFU/g, where moldy notes and mustiness can already be detected. The flavor and smell profiles turn bitter, harsh, and acrid like musty hay or stale urine.

In the beginning of mold and bacterial infestation, the flower looks slimy and wet, but as time goes on, the flower gets dried out as mold and bacteria use up all available moisture, and gets pale and dull discoloration. Over time, terpenes and cannabinoids are altered and masked, as well as visual and odor characteristics. Overall, the contaminants are contributing to cellular deterioration and degrading the quality of the flower as it accumulates microbial metabolites and other microbial waste products.

Through research, market audits, and individual studies, it is estimated that at retail level 70% or more of products will fail state safety limits due to microbial contamination. This is no surprise as mold and bacteria will continue to grow in the package at over 20% per week if the cannabis is not stored in a very low oxygen environment. Some of the testing has found, on average, cannabis at over 120,000 CFU/g and it is degrading and composting inside the package. At such high levels, similar to the food industry above 100,000 CFU/g, cannabis should not be considered fit for human consumption or use and should be directed to extraction. Alarmingly, some products have shown to be at 800,000 CFU/g and higher and are still being consumed by buyers.

What is VIST?

VIST is a healthcare technology solution setting the standard of excellence for quality and purity of cannabis. We provide microbial decontamination and aseptic modified atmosphere packaging to preserve the quality and freshness of cannabis while protecting consumers. Our mobile fleet of vans bring our technology directly to cultivators' licensed facilities, where we will decontaminate and package their cannabis under their roof. VIST's solutions are:

1. **CryoPasteurization.** A natural microbial decontamination process, CryoPasteurization kills microbial contaminants to safe pasteurization levels (well below the 10,000 CFU/g threshold), while maintaining the integrity of cannabis and protecting terpenes and cannabinoids. The system is capable of operating in CryoSterilization mode as well for complete sterilization of the product.
    a. Benefits of CryoPasteurization: Never irradiated and no harmful chemicals or oxidants; preserves organoleptics, cannabinoids, and terpenes; safe, effective, and natural process.
    b. CryoPasteurization is a solution that can occur before or after testing, depending on the preferences of the growers. Before microbiological testing, our system will ensure that cannabis is pasteurized to within the threshold requirements and it will provide peace of mind. After microbiological testing, the cannabis can go through CryoPasteurization to clean and decontaminate the product after failure as well.
    c. CryoPasteurization can be used as the 6 log kill step as part of the everyday standard operating procedure (SOP) to guarantee safe and clean cannabis to consumers. This same pasteurization safety practice was implemented in 1906 for

raw milk, and for over 100 years has saved countless lives and protected consumers ever since as it expanded to other susceptible products in the food and drug supply.

2. **Aseptic Modified Atmosphere Packaging System (AMAPS).** Using a Class-100 Clean Room environment, a precision low oxygen atmosphere, and high barrier packaging, AMAPS protects quality and freshness of cannabis by stopping microbial growth and oxidation of sensitive terpenes and cannabinoids.
    a. Aseptic Modified Atmosphere Packaging ensures that there will be no continued microbial contaminant growth over time. This allows cannabis to maintain potency levels on the label through the end of shelf life.

Recommendations

We are requesting the State of Oregon to consider adopting the same standards that the FDA and FTC use today for food, pharmaceutical, and medical products which will likely be imposed upon federal legalization. An early adoption is critical for all cannabis growers to begin accommodating these changes so that they are prepared and already in line with regulations. This ensures the safety of consumers and the integrity of the cannabis industry in Oregon.

Specifically, we propose:

1. **Protection of Consumers' Health.** Implementing microbial testing standards including Total Yeast and Mold Counts and Total Aerobic Counts and provide a maximum threshold of 10,000 CFU/g that would occur at representative sampling for state testing before it is packaged and sent to retailers. This testing would test for microbiological contaminants, like yeast, mold and bacteria. We also agree that testing standards should include pathogenic testing, aflatoxin and mycotoxins, and heavy metals.
    a. We recognize that current packaging capabilities of producers and retailers may cause microbials to continue to grow after state testing. Due to that, we recommend that the end of shelf life maximum threshold is 20,000 CFU/g (same standards for milk). However, the cannabis industry is still in its infancy, and packaging capabilities are not as advanced or readily available. This 20,000 CFU/g maximum provides for a 60-90 day shelf life after pasteurization and can be extended to one year with the use of VIST's AMAPS low oxygen atmosphere.Starting the thresholds now will allow for businesses to look at options sooner rather than later so that they are prepared for more stringent requirements upon federal legalization.
2. **Implementing a 6 log (pasteurization) Kill-Step.** In the food industry, almost all susceptible food products go through a kill-step process that destroys pathogens and microbes. We recommend including a 6 log (pasteurization) kill-step of microbes in the production process of cannabis after curing and prior to packaging and testing.

a. We suggest that this kill step occurs before sending cannabis flower to state testing. This will provide peace of mind for both growers and consumers, knowing that their products have been cleaned and will have reduced microbial failures. This kill-step may also occur after state testing.
b. VIST's CryoPasteurization and AMAPS solution would provide an excellent post-cultivation step. Not only do we clean the cannabis, but we immediately aseptically package it in bulk bags which provide a controlled modified atmosphere to preserve the cannabis.
c. Consider adding a spoilage definition of 100,000 CFU/g for raw cannabis where above that level, the product must go to extraction. Below that threshold, the product must be pasteurized or decontaminated to less than 10,000 CFU/g and the end of shelf life determinant is 20,000 CFU/g in the package. This is similar to the spoilage definitions for milk and other food and pharmaceutical products under the FDA.

3. **Failing a State Microbial Test - Language Change.** We propose a language change that will allow for a third option if cannabis fails state testing. If cannabis flower fails state testing, the current protocol is to send it to extraction or to be destroyed. This leads to a 70% loss in product value when the flower goes to extraction, leading to economic losses for cultivators. We propose the language change that will allow for a process to pasteurize cannabis without changing its form in order to meet state testing level thresholds of 10,000 CFU/g. This language change would accommodate for a pasteurization process, instead of immediately moving to extraction below the 100,000 CFU/g level.
    a. In addition to VIST, there are other solutions that provide a means of cleaning cannabis after failing state testing. VIST's CryoPasteurization system kills microbes without changing the form of the flower and also preserves terpenes and cannabinoids. The end result is cleaned cannabis flower that will pass state testing and be safe for consumers.
    b. CryoPasteurization as a cleaning solution will allow cultivators to realize the profits that would have otherwise disappeared due to extraction.
4. **Spoilage Criteria Defined.** We recommend including language that determines the spoilage criteria of cannabis. It is imperative to include TYMC and TAC as a quality indicator for cannabis in order to ensure consumer safety.
    a. Based on research, we suggest that, similar to raw food products, raw cannabis should not be allowed above 100,000 CFU/g and should be moved to extraction purposes only. Between 10,000 to 99,999 CFU/g, cannabis flower can go through a remediation/pasteurization process that will reduce the plate counts to below the 10,000 CFU/g threshold. The maximum allowable threshold should be 10,000 CFU/g at state testing. For a short period, until packaging capabilities become more advanced for cannabis, the maximum end of shelf life threshold at retail level is 20,000 CFU/g.

b. Testing for microbiological contaminants should include Total Yeast and Mold Counts (TYMC) and Total Aerobic Counts (TAC) to protect consumers from heavily contaminated cannabis as well as mycotoxins, heavy metals, and other pathogens.

We appreciate the opportunity to provide comments in regard to the proposed regulations in Oregon for the cannabis industry. VIST strives to protect both consumers and cannabis and we encourage governmental response to ensure that the quality and safety is instilled at every step of the distribution and retail process of cannabis. Thank you for your diligence.

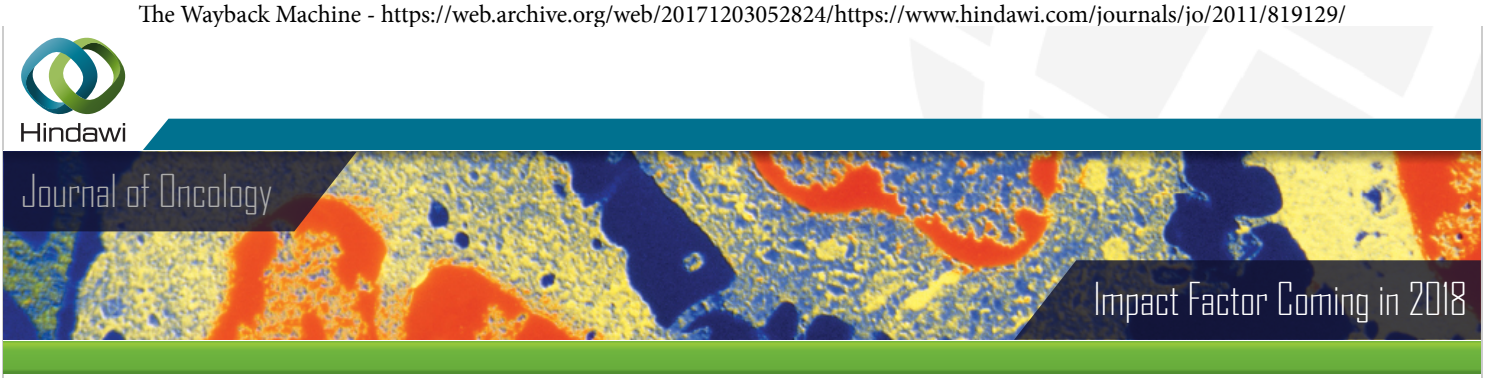
Christian Hageseth
Chief Operating Officer at VIST Labs
christian.hageseth@vistlabs.com
(303) 520-4844

VIST

VIST Labs, LLC Headquarters
1515 Woodfield Rd, Suite 740
Schaumburg, IL 60173

References & Additional Studies

- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3136185/
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7516211/#B51
- https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd
- https://www.fda.gov/food/laboratory-methods-food/bam-chapter-18-yeasts-molds-and-mycotoxins
- https://www.researchgate.net/publication/236288998_Fungal_Contamination_of_Tobacco_and_Marijuana
- https://www.scientificamerican.com/article/cigarettes-smoking-bacteria-infection-pathogen/
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-cut-fruits-and-vegetables
- https://cannabis.ucdavis.edu/news/uc-davis-study-identifies-potentially-lethal-bacteria-and-mold-cannabis-grown-northern



Journal of Oncology
Volume 2011 (2011), Article ID 819129, 13 pages
http://dx.doi.org/10.1155/2011/819129

Abstract
Full-Text PDF
Full-Text HTML
Full-Text ePUB
Full-Text XML
Linked References
Citations to this Article
How to Cite this Article
Complete Special Issue

Review Article

Cigarette Smoke, Bacteria, Mold, Microbial Toxins, and Chronic Lung Inflammation

John L. Pauly and Geraldine Paszkiewicz

Department of Immunology, Roswell Park Cancer Institute, Elm and Carlton Streets, Buffalo, NY 14263, USA

Received 16 November 2010; Revised 28 February 2011; Accepted 20 March 2011

Academic Editor: Venkateshwar Keshamouni

Abstract

Chronic inflammation associated with cigarette smoke fosters malignant transformation and tumor cell proliferation and promotes certain nonneoplastic pulmonary diseases. The question arises as to whether chronic inflammation and/or colonization of the airway can be attributed, at least in part, to tobacco-associated microbes (bacteria, fungi, and spores) and/or microbial toxins (endotoxins and mycotoxins) in tobacco. To address this question, a literature search of documents in various databases was performed. The databases included PubMed, Legacy Tobacco Documents Library, and US Patents. This investigation documents that tobacco companies have identified and quantified bacteria, fungi, and microbial toxins at harvest, throughout fermentation, and during storage. Also characterized was the microbial flora of diverse smoking and smokeless tobacco articles. Evidence-based health concerns expressed in investigations of microbes and microbial toxins in cigarettes, cigarette smoke, and smokeless tobacco products are reasonable; they warrant review by regulatory authorities and, if necessary, additional investigation to address scientific gaps.

1. Introduction: Chemical and Biological Components of Tobacco and Smoke

For many years, scientists have undertaken studies to define the chemical composition of green tobacco leaf, cured-fermented-stored tobacco leaf, and tobacco smoke with the intent of identifying chemicals that may pose a significant health risk [1–4]. An illustration has been prepared of the annual increase, from 1954 to 2005, in the total number of tobacco smoke chemicals that have been identified [4]. Today, there is a consensus of opinion that cigarette smoke consists of at least 5,300 different chemicals [4]. These chemicals are present in the complex aerosol that consists of a heterogeneous mixture of gas- (vapor-) phase and particulate- ("tar-") phase components [1–4].

Detailed listings of the chemicals in mainstream and sidestream tobacco smoke are available, and an assessment of their propensity for harm has been presented; a partial listing of references is included [1–4]. Most of the chemicals, toxicants, and carcinogens in tobacco smoke arise from the burning (pyrolysis) of the tobacco [1, 2, 4]. The potential for harm has also been studied for chemicals that do not arise from the burning of tobacco. The chemicals include metallic and nonmetallic elements, isotopes, and salts [1, 2, 4]. In addition, pesticides and other intact agrochemicals have been identified in tobacco smoke [1, 2, 4]. Also included in this tabulation of chemicals in smoke are menthol and flavorants [4].

In 1985, Hoffmann and coworkers, who had studied the chemical composition of tobacco smoke for many years, began formulating a list of chemicals that were designated as biologically active, carcinogenic, cocarcinogenic, or tumorgenic, reviewed previously in [4]. The tabulation was revised and became the basis for the list of "*Hoffmann Analytes*" [4]. In 1985, different working groups met to identify those chemicals in tobacco smoke that are most likely to be carcinogenic to humans as defined by criteria of the International Association for Research on Cancer (IARC), an intergovernmental agency forming part of the World Health Organization, and by the US National Toxicology Program (NTP) [1, 2, 4].

2. The Changing Cigarette

The identification, classification, and concentration of the various chemicals in cigarette smoke have been challenged by changes in the design of cigarettes. A comprehensive review of "The Changing Cigarette" was published by D. Hoffmann and I. Hoffmann in 1997 [5].

Subsequently, other investigators addressed changes in cigarettes and their potential for risk [6–12]. By way of example, a partial tabulation of changes in cigarette includes (a) increased cigarette length (85 mm king sized and extra long "120's") and, for some brands, reduced circumference (23 mm "slim" cigarettes), (b) variation in the blend of natural tobaccos of diverse types, country of origin, and curing processes, relative percent tobacco leaf (lamina) versus tobacco ribs/stems, and tobacco weight per rod, (c) incorporation of manmade tobacco, sometimes referred to as reconstituted or "sheet" tobacco, (d) introduction of additives to the tobacco (casings) that include diverse flavorings (licorice and honey), humectants to retain tobacco moisture, and menthol to ameliorate smoke irritation and promote smoking acceptance by youngsters and "starters" (e) addition of ammonia, to facilitate "freebasing" the nicotine to enhance the pharmacological effect (impact), (f) application of diverse glues and printing ink, (g) configuration of diverse cigarette filter materials (cellulose acetate, paper, or combination of both), (h) alteration of filters with charcoal and schemes whether the carbon was dispersed throughout the filter plug or retained in a filter cavity, (i) variation in filter design (filter length, fiber packing/crimping, fiber density, and filter ventilation) to effect tar delivery (full flavor cigarettes versus ultralight low-tar cigarettes), (j) paper type, paper porosity, with burn accelerators to promote burning, or with modifications to reduce the propensity for sustained burning and affect a "fire safe" designation, and (k) diverse methodologies to reduce "tar" and nicotine yields in mainstream smoke of cigarettes that have been smoked mechanically [6–12].

The topic of "*The Changing Cigarette*" has been addressed and summarized in a recent report of the Surgeon General entitled "How Tobacco Smoke Causes Disease" [13]. A review of the scientific and medical literature has shown that (a) changing cigarette designs over the last five decades, including the introduction of cigarette filters and low-tar cigarettes, have not reduced overall disease risk among smokers and may have hindered prevention and cessation efforts, (b) there is insufficient evidence that novel tobacco products reduce individual and population health risks, and (c) the introduction of novel tobacco products that are marketed as reduced-risk cigarettes may encourage tobacco use among youngsters. These changes have challenged tobacco policy and regulation [13].

3. Tobacco and Harm Associated with Microbes

Our review of the aforementioned writings [1–4] and many other related reports, addressing chemicals in tobacco smoke of cigarettes have shown that the writings do not address the propensity for harm that may be associated with microbial elements of smokeless and smoking tobacco articles. A partial listing of tobacco-associated microbial elements include bacteria (Gram positive and Gram negative), bacterial spores, fungi (yeast and mold), fungal spores, cell wall components (certain glucans and flagellum), and diverse microbial toxins that include exotoxins and endotoxins. Examples of bacterial-derived toxins include endotoxins (lipopolysaccharide, LPS; inflammatory factor) and fungal-derived mycotoxins (aflatoxins, AF type B1; human carcinogen) [1–4].

There exists today a concern of the potential health risks associated with diverse microbial elements that are known to exist in smoking and smokeless tobacco products that are currently being marketed. This subject has not been addressed in the context of national tobacco control policy or regulatory authorities.

Harm is to be recognized as persistent or chronic inflammation. Inflammation is mediated by different leukocyte subsets and different secreted factors (Figure 1). Inflammation not only establishes a microenvironment that fosters the malignant transformation and tumor growth but also promotes microbial colonization.

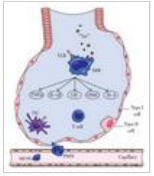


Figure 1: A schematic view of an alveolus that depicts the effect of inhaled tobacco smoke on the terminal (respiratory) structure of the lung. Particulate matter "Tar" in tobacco smoke is inhaled deep into the lung where it is recognized by macrophages. The macrophages arise from the blood monocytes that migrate into the lung where they undergo differentiation and maturation. Macrophage phagocytosis of the chemical-rich "Tar" evokes the production of diverse proinflammatory mediators (for details, see Figure 1). Macrophages have toll-like receptors (TLR) that recognize diverse microbes and toxins (LPS is recognized by TLR-4). Shown in this illustration is the production of five proinflammatory cytokines: tumor necrosis factor, type alpha (TNFα), interleukin 1-beta (IL-1β), leukemia inhibitory factor (LIF), oncostatin M (OSM), and Interleukin-4 (IL-4). These soluble factors interact with other cells of the lung, and the response of these cells is thought to accelerate, amplify, and prolong pulmonary inflammation. The target cells may include T cells. The T cell that is depicted herein is representative of many different T cell subsets, including T helper cell subsets Th1, Th2, and Th17. Type I epithelial cells are the major cells lining the alveolar space, and facilitating O_2/CO_2. The type I cells are spread out and cover about 90 to 95% of the alveolar surface. The type II cells form only 5 to 10% of the surface but produce surfactant proteins. Polymorphonuclear leukocytes (PMN) mediate inflammation in multiple ways, including the production of an oxidative burst. Dendritic cells (DC) are professional antigen-presenting cells; they also mediate inflammation.

4. Research Objectives

The goal of this paper is to profile the scientific and medical literature addressing microbes in tobacco with the intent to determine whether there is sufficient evidence to warrant additional investigations to assess propensity for human harm. The impetus for undertaking this work was derived in part from the fact that several teams of investigators, including our own, have published observations during the last few years that suggest microbial elements maybe harmful to tobacco users.

Notable in a first analysis of the literature on the microbiology of tobacco we discovered that there were few recent reports (1990 to 2010) in peer-reviewed, mainstream, scientific and medical journals by scientists of tobacco companies. By way of example, Philip Morris has contracted the Life Science Research Office, Inc., (LSRO, Bethesda, MD), to identify methods to evaluate tobacco products and with a particular focus on identifying research schemes and assays for assessing reduced-risk tobacco articles [14]. Three monographs published by LSRO in 2007 detailed the chemicals

to be assayed and recommended procedures. The subject of microbial flora and microbial toxins was not addressed, nor were schemes and methodologies for the assessment of tobacco associated bacteria, mold, or microbial toxins [14].

Therefore, the question arose as to whether the issue of health risks associated with microbial elements in smokeless and smoking tobacco was not investigated by laboratory scientists working at the tobacco companies or whether the subject was studied and the information withheld as private and confidential. The paucity of the literature on health risks associated with microbes in smokeless and smoking tobacco is to be contrasted to the numerous reports by tobacco scientists researching other health-related issues, such as potential reduced-risk exposure tobacco products (PREPS) [15].

5. Perspective and Limitations

The authors are immunologists and have an active research interest in addressing tobacco-associated chronic pulmonary inflammation. It is acknowledged that immunological responses and inflammation would not be a primary interest by other investigators whose primary interests are in the disciplines of microbiology/metagenomics, aerosol-associated inhalation toxicology, infectious diseases, and clinical pathology (oral and lung). Also, the work presented herein is limited in scope. The authors retrieved numerous documents from databases, but space restrictions permit citing but a few of the writings. Also, many of the writings were internal documents and were not subjected to peer-review. Some documents cited are old and are addressed herein to provide a historical perspective. Lastly, the documents are fragmented and it is recognized that conflicting findings and interpretations may be presented by competing tobacco companies.

6. Literature Search

A computer-based structured search of the literature was conducted. The study scheme included a search of the literature from PubMed (http://www.ncbi.nlm.nih.gov/pubmed) and Scopus (http://www.scopus.com/home.url). Also, included was a search of Google (http://www.google.com/). A search was also made of patents in the database of the US Patent and Trade Office (http://www.uspto.gov/). In addition, searches were made for documents that were released by the tobacco companies and made public as a consequence of the tobacco Master Settlement Agreement. To this end, we searched database records of over 11 million documents in the digital archive that were established and which are maintained currently at the University of California, San Francisco (http://legacy.library.ucsf.edu/). We also searched the database from Tobacco Documents (http://tobaccodocuments.org/).

The searches were performed using conventional telegram-style search short-string text formulations with Boolean operators as described in PubMed. Illustrative key search words were bacteria, mold, fungi, yeast, tobacco, smoke, endotoxin, mycotoxin, cured, fermented, lipopolysaccharide, aflatoxin, and microbiology. We also used unique search words, such as author's name, project designation, report codes, cigarette brands, and Bates number. The references cited in the retrieved literature were reviewed to identify other topic-specific writings Table 1.

Table 1: History of investigations of microbes and microbial toxins in tobacco and tobacco products.

7. Tobacco-Associated Chronic Inflammation

Chronic inflammation is associated with malignant transformation, tumor growth, and, possibly, tumor metastasis, reviewed in [44–52]. Examples of the association of cancer with chronic inflammation include (a) lung cancer and cigarette smoke (aerosol), (b) malignant mesothelioma and asbestos (fibers), (c) stomach cancer and *H. Pylor*i (bacteria), (d) malignant melanoma and ultraviolet sun light (irradiation), (e) liver cancer and aflatoxin (mycotoxin), and (f) cancer of the uterine cervix and human papilloma virus. Thus, malignancy at diverse body sites, and of various tissues, is associated with chronic inflammation provoked by assorted items that include smoke, bacteria, fibers, irradiation, toxins, and viruses.

8. Cigarette Smoke, Chronic Inflammation, and Impaired Immunity

Cigarette smoke is known to induce chronic inflammation of the lung [53–60]. More recently, a substantial body of information has been obtained to suggest that long-term cigarette smoking may not only have an adverse effect of systemic immunity but also skews both innate and adaptive immune responses [61–65].

9. Study Rationale: Evidence-Based Health Risks of Tobacco-Associated Microbes

Concern has been expressed by many investigators that microorganisms on cured tobacco might represent a health risk. By way of example, in 1968, Wood [66], a scientist at the British American Tobacco Company, wrote a 37-page report addressing the possible transfer of viable microorganisms into mainstream smoke. In this internal document, he notes that cured tobacco, of various types, has long been known to contain bacterial spores. Likewise, Wood [66] and others [23] have addressed the possibility that tobacco-associated mold may also represent a health hazard to smokers. Support for this concern was derived in part from a paper published in *Science* by Forgacs and Carll two years previously in which they reported the identification of toxic fungi in tobacco [23]. In the *Science* paper, the investigators exposed mice to smoke from fungally contaminated hay. The mice developed pulmonary emphysema and other pathological conditions; in contrast, mice exposed to smoke from sterile, uninoculated hay remained normal clinically. In a letter to the Associate Scientific Director of the Council for Tobacco Research, dated 1964, Forgacs, with more than 16 years of research experience as a mycologist, states that he had examined mycologically a number of tobacco products, including cigarettes that had been purchased on the open market [67]. Forgacs observed that the tobacco of all cigarettes contained fungal mycelia

and spores [67]. In part, the origin of his health concern is based upon the knowledge of (a) widespread fungal contamination of tobacco products, (b) heat stability of the mycotoxins; (c) known animal toxicity, (d) reasonable assumption that some of the fungi are carcinogenic, and (e) potency at low doses, see also [68].

Wood argues that

> "[W]hile it is quite impossible to deduce, from this (mouse) experiment, the likely effect of smoke from a cigarette containing fungally contaminated tobacco, the implications are sufficiently important to warrant some consideration of the role which micro-organisms may play with regard to smoke toxicity. For instance, it is possible that viable spores might be transferred to mainstream smoke and thus enter the lungs; pathogenic species, even in small numbers, could clearly have harmful effects, while very large number of otherwise harmless micro-organisms might lead to a significant concentration of genetic material. Alternatively, during the vegetative stage of their residence on tobacco the micro-organisms might produce toxins which could transfer direct to smoke or metabolites which on burning could give toxic smoke constituents."

The report by Wood also describes some preliminary experiments which were undertaken to show whether bacterial or fungal spores could transfer into tobacco smoke. Two schemes were used to trap the cigarette smoke; these were a test tube bubbler and a micropore filter. These samples from the bubbler and the filter were tested for the growth of microorganisms. Growth of microbes was observed; however, technical problems were encountered including poor reproducibility and smoke toxicity. The results were inconclusive. Our search for subsequent studies by Wood addressing this subject failed to identify subsequent experiments or published reports. Studies by Slutzker et al. were negative [69]. In 1967, Curby reported to The Council for Tobacco Research the results of comparative studies that he had undertaken to determine the microbiological activity in the smoke from filter and nonfilter cigarettes. Different popular brands of cigarettes were obtained from local vendors in Brookline, Mass, USA. Comparative analyses were made of bacteria released from cigarettes that had been "cold smoked" (not lit) or smoked in the usual manner (lit). The tobacco smoke collection system was tested for sterility by means of conventional microbiology culture procedure and by means of electronic analyses of particle size and number. Viable bacteria were identified in the smoke from all cigarettes tested. The number of liberated organisms was much greater when the cigarette was burning [24, 25].

Before profiling more recent studies, a brief overview is warranted of what many internal documents of the tobacco industry have entitled the "*Microbiology of Tobacco.*"

10. Microbiology of Tobacco

The *"Microbiology of Tobacco"* has been the focus of many studies. It was not surprising to learn from our paper that most of all the major tobacco companies have studied this issue for many years. Listed below are varying topics addressing bacteria, mold, and mycotoxins in tobacco and references

(a) chemical and microbiological changes during curing [16, 19, 70–75],
(b) bacteria in cigarettes; product comparison (also, see below) [17, 76–79],
(c) databases of tobacco microbes [33, 40, 80],
(d) tobacco microbe control [81],
(e) microflora community of tobacco [82–88],
(f) quantitative studies of tobacco microflora [89–91],
(g) growth of mold in stored tobacco [26, 92],
(h) growth of *Aspergillus* from tobacco [93–95],
(i) microbial degradation of nicotine [18, 96],
(j) examination of cigarettes from mold-damaged and nondamaged tobacco [97],
(k) isolation of viable fungi from snuff [98],
(l) sterilization/treatment to remove NNK [37, 99–105],
(m) removal of harmful toxins on tobacco [35, 95],
(n) inhibiting mycotoxin production [106],
(o) microbiology of cigarettes, pipes, cigars, and snuff [27–30, 107–111].

From about the early 1970s, extensive research was conducted on the *Microbiology of Tobacco.* Many reports reflected the interest of the major tobacco companies. These studies sought to identify different bacteria and molds and to count the number of colony-forming units (CFU) during processing. The number of bacteria and molds present in green, freshly harvested tobacco was compared to that of various stages of curing, fermentation, and long-term storage. In many cases, more than one million bacteria were found in a gram of tobacco (a 100 mm cigarette has about 0.9 grams of tobacco). Comparative studies included various types of tobacco (Bright and Burley) and different curing methods (field versus flue cured). In these studies, profiles were established for leaves of the different types of tobacco that had been picked from various positions of the plant. Diverse environmental conditions were evaluated, and these included variations in temperature and moisture. Analyses were made of the number of bacteria in popular brand cigarettes. In many instances, the number of bacteria of a particular company's brand was compared to brands marketed by competitors. In addition to cigarettes, studies were performed for cigars and snuff. Considerable effort was devoted to defining procedures for the sterilization of tobacco to reduce or prevent the growth of mold. The methods used included (a) washing methods using various solutions (bleach), (b) irradiation with microwave, ultraviolet light, and gamma radiation, (c) exposure to various gases, and (d) treatment with different antibacterial and antifungal agents (antibiotics). One scheme was to destroy all of the bacteria on freshly harvested green tobacco leaves and then seed the leaves for fermentation using selected colonies from in-house batch-scale production. Quality control of the tobacco was important as high levels of mold produced an unacceptable "off-taste."

11. Pathogenic Bacteria of Chewing Tobacco

Studies have been conducted by investigators of the tobacco industry (see above) and health community to address the potential of bacteria, molds, yeast, and microbial toxins found in different types of smokeless tobacco (snuff, snus, and long cut) [20, 26, 31, 43, 112, 113].

In 1951, Dynert published in *The New England Journal of Medicine* a case report of a patient with chronic bronchitis. *Pseudomonas aeruginosa,* often colonized in COPD patients, and a few colonies of *Staphylococcus aureus* were identified in bacteriological examinations of the subject's sputum [20]. The patient used snuff, and it was theorized that the snuff may have been the source of the pathogens. A study was then undertaken of 22 samples of previously unopened packs of snuff. The following microorganisms were grown from more than 50% of the snuff samples: *Bacillus rubitilles*, *Staphylococcus aureus* (coagulase positive), *Staphylococcus albus* (coagulase positive), *Pseudomonas aeruginosa*, *Staphylococcus aureus* (coagulase negative), and *Staphylococcus albus* (coagulase negative).

In 1991, Varma reported the isolation of nine species of *Aspergillus* in stored leaves of chewing tobacco [112]. Approximately 18 of the Aspergilli were found to be mycotoxigenic. All aflatoxigenic strains of *A. flavus* produced aflatoxin B_1. Patulin and ochratoxin were produced by *A. ochraceus*. Sterigmatocystin was produced by three different strains.

Warke [103] studied the microbiological quality of chewable, often sweet, tobacco mixes known as "Gutka" used by millions of children and adults in India where it is made and often exported. Of the 15 samples studied, all contained aflatoxins B_1, B_2, and G_2. Samples exposed to ^{60}Co radiation displayed a marked reduction of viable CFU. Sterilization of tobacco in the manufacturing has been described in US Patents [105].

In 1992, Rubenstein reported the identification of large number ($>10^6$ CFU) of a *Bacillus* species in chewing tobacco sold in the USA [31]. Supernatants of the cultured bacteria evoked a plasma exudate in studies in which the supernatant was instilled into an intact hamster cheek pouch.

12. Pathogenic Bacteria of Cigarettes

Some bacteria grow in unique microenvironments, and some are difficult to grow using traditional broth- and agar-based methods. This technical difficulty may also apply to growing bacteria that have adapted to unique conditions that develop during the curing and fermentation of tobacco. Accordingly, it is believed that conventional methods may not accurately define the microflora of diverse tobacco products [43, 113]. Consequently, there may be an incomplete understanding of the bacterial diversity in the tobacco of cigarettes and also the impact these microbes and microbial toxins may impose on the smoker [113].

Recently, the bacterial metagenomic of cigarettes were characterized using a 16S rRNA-based taxonomic microassay as well as traditional cloning and sequencing methods. The brands included Camel, Marlboro, Kool, and Lucky Strike. The results of this study showed that the number of microorganisms in cigarettes may be as vast as the number of chemicals in these products. Fifteen classes of bacteria were identified [113]. Particularly noteworthy was the identification of a broad range of potentially pathogenic microorganisms detected. More than 90% of the tobacco samples from the cigarettes contained *Actinetobacter*, *Bacillus*, *Burkholderia*, *Closteridium*, *Klebsiella*, *Pseudomonas aerogenosa*, and *Serratia*. Other bacteria that are known to be potentially pathogenic to humans and detected using the metagenomic technology were *Campylobacter*, *Enterococcus*, *Proteus*, and *Staphylococcus* [113].

Reported also in 2010 were the results of an investigation of the diversities of unaged and flue-cured tobacco leaves using a 16S rRNA sequence analysis scheme [43].

Others have reported the identification of potentially pathogenic bacteria in commercial cigarettes. One study was undertaken to assess the bacterial diversity of cigarettes that were thought to be linked to severe pneumonitis in US military personnel deployed in Operation Iraqi Freedom [38]. Eight species of *Bacillus*, including five new species, and one new species of *Kurthia* were isolated from the cigarettes. Some of these species have been identified elsewhere to cause hypersensitivity pneumonitis and other respiratory syndromes [38]. This study was of particular interest to many because the cigarettes were made in Iraq and not manufactured by a major tobacco company. Undertaking this investigation, the question arose as to whether the cigarettes that had been purchased by soldiers from street vendors had been intentionally altered by adding pathogenic bacteria and/or mold. This theory was disproven.

Another study was conducted by a group of investigators in Sweden who characterized the bacterial and fungal community in warehouse tobacco [41].

We have reported previously the establishment of a novel bioassay which showed that bacteria were grown routinely from a single flake of tobacco that had been placed on the surface of a sheep blood agar plate [42]. Of eight popular brands of cigarettes, bacteria grew from almost all (>90%) of the flakes. Similarly, bacteria were grown from a single flake, and also with a high frequency, from tobacco that had been retrieved from cigar filler and from smokeless tobacco (snus, snuff, and long cut). Some bacteria induced hemolysis of the blood in the agar dishes. The destruction of the red blood cells was readily visible as a yellow zone surrounding a single tobacco flake. Expanding studies documented the hemolysis of human blood in agar or nutrient broth cultures. Thus, as discussed later, bacteria could be carried deep into the respiratory tract by a single tobacco flake sucked from the cut surface of a cigarette filter and transported into the bolus of smoke that is inhaled deep into the lung. A single tobacco flake may be envisioned as a matrix for delivering diverse bacteria into the respiratory tract of an immunologically compromised long-term smoker.

13. Cigarettes with Mold

Mold has been identified in the tobacco of popular brand cigarettes, and concern has been raised as to the propensity of these microbes as a health risk to the smoker. Presented herein is a partial listing of papers that have identified mold in cigarettes [78, 114–116] and in marijuana [116].

As early as 1971, Papavassiliou and coworkers concluded that "[C]igarettes are contaminated with various fungi." They studied cigarettes that were manufactured in the USA, Canada, England, France, Belgium, Germany, Jordan, and Egypt. Hundreds of strains of fungi were isolated. The Greek scientists demonstrate that the most prominent fungi were *Aspergillus* (28 strains from Greek cigarettes and 35 strains from other countries). They raised the question as of the association of the fungi with allergies but commented that this issue has not been resolved [114].

In 1983, Kurup and colleagues reported the identification of allergenic fungi in smoking materials and discussed the health implications of their findings [115]. Concern has been expressed as to the health risks associated with mold in cigarettes.

Writing in the Journal of the American Medical Association, Verweij et al. addressed the propensity of heath risks associated with fungal contaminates of tobacco and marijuana [116]. They concluded that "[A]ll cigarette brands tested ($N = 14$ brands) had some degree of fungal contamination, although not every cigarette was found to have a positive culture."

14. Transfer of Tobacco Flake to Mainstream Smoke

The filter of a cigarette is often contaminated with loose tobacco flakes, tobacco fines, and tobacco dust. In one examination, the filters of 11 brands of cigarettes were examined in freshly opened packs. For all brands, cigarettes were observed with tobacco flakes on the filter. Examination of the filters with the naked eye showed that 127 of 208 (61.1%) of the filter had tobacco particles [42]. The release of tobacco flakes into mainstream smoke has been described previously [21, 22].

The tobacco flakes that contaminate the filter arise from tobacco that escapes from the nonfilter, sometimes called the distal, end of the cigarette. Most probably the flakes are jarred loose during manufacturing, shipment, and daily transportation, especially in a pack in which more than one-half of the cigarettes have been used [117, 118].

The release of flakes from the cut surface can readily be demonstrated by comparing the cut surface of the filter before and after smoking the first puff. The single flake may be viewed as a matrix for carrying bacterial and fungal agents in mainstream tobacco smoke. Thus, the burning of the tobacco during cigarette smoking does not exclude the exposure to tobacco-associated microbes and microbial toxins.

Bacteria are also released from the barrel of the cigarette. This was demonstrated in investigations in which a cigarette was rolled over the surface of a nutrient agar dish.

15. Endotoxin (LPS) in Mainstream and Sidestream Tobacco Smoke

In 1999, Hasday and his colleagues reported the identification of bacterial endotoxin as an active component in cigarette tobacco and cigarette smoke [34]. The authors showed that the dose of LPS delivered from smoking one pack of cigarettes was comparable to that of the LPS that had been previously shown to be associated with adverse health effects in cotton textile workers. With the knowledge that LPS is one of the most potent inflammation-inducing agents, the work by Hasday attracted considerable attention, reviewed in [32]. In 2004, Larsson et al. reported that they were able to demonstrate unequivocally that high levels of LPS are inhaled during active cigarette smoking and, more importantly, that environmental tobacco smoke may involve inhalation of amounts of endotoxin that are dramatically greater than those existing in indoor environments free from tobacco smoke [36]. In 2006, these findings were confirmed and extended [39]. Particularly notable is that studies of Larsson and colleagues used a mass-spectrometry-based assay that circumvents the problems often associated with the biologically based LPS assay.

16. Analysis of Findings and Policy Recommendations

The results of this literature review have documented that the tobacco microflora has been the subject of many studies by investigators of tobacco industry and academic communities. During the last 50 years, there has been an imbalance, however, in the attention devoted to addressing the identification and propensity of the harm of tobacco- and tobacco-smoke-associated chemicals and in the attention devoted to characterizing microbes and microbial-derived factors.

Ample information has accumulated to suggest that microbes and microbial-derived factors may contribute to the health risks of smoking and smokeless tobacco products. Moreover, the microbes may facilitate microbial colonization of the mouth and airway, the induction of chronic inflammation through the activation of diverse leukocyte subsets, alteration of the tissue microenvironment, and microbial-toxin-induced pathologies. The current health concerns recently expressed by investigators of various disciplines, and with different research interests, in peer-reviewed published research articles are reasonable and validate that additional investigation of the microbiology of tobacco is warranted. The findings reported herein relate to National Tobacco Control Policy and specifically FDA Regulation of Tobacco Products [119].

Based upon the information obtained in this paper, we recommend the following for consideration and possible regulatory action.

(1) Tobacco products should be assessed with the knowledge that they contain bacteria, mold, and microbial toxins.
   (a) In this context, the designation of tobacco products is to include conventional and novel products that contain tobacco, including items which are smoking and smokeless tobacco articles.
   (b) National and international registries of known human carcinogens should not be used as the sole criteria for assessing tobacco-associated human health risks. Any and all tobacco-associated agents that induce any human pathology should be included in risk assessments.
   (c) Tobacco in smoking and smokeless tobacco articles should be assessed for their propensity to induce chronic inflammation. Chronic inflammation is known to be induced by diverse bacteria (Gram positive and Gram negative) and fungi, living or dead, whole or fragmented, and intracellular and membrane components. Chronic inflammation is known also to be induced by diverse toxins of bacteria and/or fungi including, but not limited to, endotoxins, exotoxins, and mycotoxins.
   (d) Chronic inflammation associated with bacteria, fungi, and microbial toxins of tobacco products should include inflammation of any and all target sites, including tissues of the mouth, nasopharynx, and lung.
   (e) In addition to chronic inflammation, harm of microbial elements of tobacco should be assessed in the context of other known tobacco-associated diseases, including chronic obstructive pulmonary disease, asthma, bronchitis, and alveolar hypersensitivity.

(2) Tobacco-specific nitrosamines (NNK) are human carcinogens that are present in mainstream smoke, sidestream smoke, and smokeless products. NNKs arise primarily from the microbial degradation of nicotine in tobacco. Different technologies have proven effective in preventing the formation of NNKs. It is recommended that these technologies be implemented and that guidelines for tobacco articles be established for reduced NNK-products.

(3) The criteria, protocols, and procedures used by the FDA in the assessment of harm associated with mycotoxins in food products should be applied to loose leaf tobacco, smoking tobacco products, and smokeless tobacco articles. Mycotoxin action levels should be established to

provide an adequate margin of safety to protect human tobacco users.

Abbreviations

AFL-B_1: Aflatoxin, type B_1
CFU: Colony forming unit
DC: Dendritic cell
IARC: International Association for Research of Cancer
IL-1β: Interleukin-1, beta
IL-4: Interleukin-4
LIF: Leukemia inhibitory factor
LPS: Lipopolysaccharide
LSRO: Life Science Research Organization
LTDL: Legacy Tobacco Document Library
MON: Monocyte
NTP: National Toxicology Program
OSM: Oncostatin M
PGE_2: Prostaglandin E2
PMN: Polymorphonuclear leukocyte
RNS: Reactive nitrogen species
ROS: Reactive oxygen species
TLR: Toll-like receptor
TNFα: Tumor necrosis factor, alpha.

References

1. M. Borgerding and H. Klus, "Analysis of complex mixtures—cigarette smoke," *Experimental Toxicology and Pathology*, vol. 57, supplement 1, pp. 43–73, 2005. View at Google Scholar
2. R. R. Baker, "Smoke chemistry," in *TOBACCO: Production, Chemistry and Technology*, D. Layten Davis and M. T. Nielsen, Eds., charter 12, pp. 398–439, Blackwell Science, 2003. View at Google Scholar
3. S. S. Hecht, "Cigarette smoking: cancer risks, carcinogens, and mechanisms," *Langenbeck's Archives of Surgery*, vol. 391, no. 6, pp. 603–613, 2006. View at Publisher · View at Google Scholar · View at PubMed · View at Scopus
4. A. Rodgman and T. A. Perfetti, *The Chemical Components of Tobacco and Tobacco Smoke*, CCRC Press, Taylor and Francis Group, Boca Raton, Fla, USA, 2009.
5. D. Hoffmann and I. Hoffmann, "The changing cigarette, 1950–1995," *Journal of Toxicology and Environmental Health A*, vol. 50, no. 4, pp. 307–364, 1997. View at Google Scholar · View at Scopus
6. G. F. Wayne and G. N. Connolly, "Regulatory assessment of brand changes in the commercial tobacco product market," *Tobacco Control*, vol. 18, no. 4, pp. 302–309, 2009. View at Publisher · View at Google Scholar · View at PubMed · View at Scopus
7. D. M. Burns and C. M. Anderson, "Do changes in cigarette design influence the rise in adenocarcinoma of the lung?" *Cancer Causes Control*, vol. 22, pp. 13–22, 2011. View at Google Scholar
8. R. J. O'Connor, K. M. Cummings, V. W. Rees et al., "Surveillance methods for identifying, characterizing, and monitoring tobacco products: potential reduced exposure products as an example," *Cancer Epidemiology Biomarkers and Prevention*, vol. 18, no. 12, pp. 3334–3348, 2009. View at Publisher · View at Google Scholar · View at PubMed · View at Scopus
9. D. K. Hatsukami, K. A. Perkins, M. G. LeSage et al., "Nicotine reduction revisited: science and future directions," *Tobacco Control*, vol. 19, no. e1, pp. 1–10, 2010. View at Google Scholar
10. H. Ito, K. Matsuo, H. Tanaka et al., "Nonfilter and filter cigarette consumption and the incidence of lung cancer by histological type in Japan and the United States: analysis of 30-year data from population-based cancer registries," *International Journal of Cancer*, vol. 128, no. 8, pp. 1918–1928, 2011. View at Google Scholar
11. M. Rabinoff, N. Caskey, A. Rissling, and C. Park, "Pharmacological and chemical effects of cigarette additives," *American Journal of Public Health*, vol. 97, no. 11, pp. 1981–1991, 2007. View at Publisher · View at Google Scholar · View at PubMed · View at Scopus
12. Brown & Williamson, "Commonly added ingredients," 1982, Bates Number 521057548/7553. Retrieved on February 22. 2011 from http://legacy.library.ucsf.edu/tid/tmx33f00.
13. A Report of the Surgeon General, "How tobacco smoke causes disease. The biology and behavior basis for smoking-attributable disease," U.S. Department of Health and Human Services, Atlanta, GA; Office on Smoking and Health, U.S. Government Printing Office, Washington, DC 20402, 704 pgs, 2010. http://www.cdc.gov/tobacco/data_statistics/sgr/2010/index.htm.
14. A. M. Bromnawell, Reports of the Life Science Research Office (LSRO), Bethesda, MD, Volume I. *Biological effects assessment in the evaluation of potential reduced-risk tobacco products*, 242 pages; Volume II. *Scientific methods to evaluate potential reduced-risk tobacco products*, 174 pages; and Volume III. *Exposure assessment in the evaluation of potential reduced-risk tobacco products*, 170 pages, 2007.

15. L. P. Carter, M. L. Stitzer, J. E. Henningfield, R. J. O'Connor, K. M. Cummings, and D. K. Hatsukam, "Review: abuse liability assessment of tobacco products including potential reduced exposure products," *Cancer Epidemiology Biomarkers and Prevention*, vol. 18, no. 12, pp. 3241–3262, 2009. View at Google Scholar

16. J. Beherns, "Die beziehungen der microorganisms zum tabaksbau and zur tabakferntation," *Zentrabl Bakteriol Parasitenk, Abt II*, vol. 2, pp. 514–527, 1896. View at Google Scholar

17. Anonymous, "Tobacco and bacteria," The London Globe, pp. 7, July 21, 1899. Retrieved on November 11, 2010 from http://query.nytimes.com/gst/abstract.html?res=FA0F14F63F5414728DDDA80A94DF405B8985F0D3.

18. H. Okino, W. C. Squires, and R. J. Reynolds, "Microbial degradation of nicotine and nicotinic acid. Part I, Isolation of nicotine decomposing bacteria and their morphological and physiological properties," 1954. Bates number 508893294/3298. Retrieved on June 24, 2011 from http://legacy.library.ucsf.edu/tid/xwr83d00.

19. A. Wiernik, A. Christakopoulos, L. Johansson, and I. Wahlberg, "Effect of air-curing on the chemical composition of tobacco," *Recent Advances in Tobacco Science*, vol. 21, pp. 39–80, 1955. View at Google Scholar

20. H. P. Dygert, "Snuff-a source of pathogenic bacteria in chronic bronchitis," *The New England Journal of Medicine*, vol. 257, no. 7, pp. 311–313, 1957. View at Google Scholar

21. W. K. Farr and A. Revere, *Examination of Whole Cigarette Smoke by Light and Electron Microscopy*, Life Extension Foundation, New York, NY, USA, 1958.

22. W. K. Farr and A. Revere, "Examination of whole cigarette smoke by light and electron microscopy," *Journal of the American Medical Association*, vol. 172, no. 4, p. 405, 1960. View at Google Scholar

23. J. Forgacs and W. T. Carll, "Mycotoxicoses: toxic fungi in tobaccos," *Science*, vol. 152, no. 3729, pp. 1634–1635, 1966. View at Google Scholar

24. W. A. Curby, "A preliminary study of the biological activity in cigarette smoke," 1967, Bates Number 11330877-0905. Retrieved on March 23, 2011 from http://legacy.library.ucsf.edu/tid/jtp6aa00.

25. W. A. Curby, "A preliminary study of the biological activity in cigarette smoke—part II," 1967, Bates Number 11330942-0973. Retrieved on March 23, 2011 from http://legacy.library.ucsf.edu/tid/stp6aa00.

26. R. E. Welty, "Fungi isolated from flue-cured tobacco sold in Southeast United States, 1968–1970," *Applied Microbiology*, vol. 24, no. 3, pp. 518–520, 1972. View at Google Scholar

27. T. G. Mitchell and British-American Tobacco Company, "Microbiological examination of tobacco products: report Number RD 969-R," 1972, Bates number 105501740/1767. Retrieved on June 28, 2010 from http://legacy.library.ucsf.edu/tid/xwp67a99.

28. P. C. Stauber and British American Tobacco Company, "Microbiology of Henri Wintermans cigar production on-site studies of the primary process at Eersel: report No. RD 925R," 1972, Bates number 107466852/6877. Retrieved on June 28, 2010 from http://legacy.library.ucsf.edu/tid/dpe66a99.

29. T. G. Mitchell and P. C. Stauber, "Methods for the microbiological examination of tobacco and tobacco products, Report Number 888—R," 1972, Bates number 105597063/7412. Retrieved on July 22, 2010 from http://legacy.library.ucsf.edu/tid/vit379.

30. Smoke Study Group, "CORESTA—Papers presented at the Kallithea Symposium," 1991, Bates number 2021551986/2194. Retrieved on July 27, 2010 from http://legacy.library.ucsf.edu/tid/zhe58e00.

31. I. Rubinstein and G. W. Pederson, "Bacillus species are present in chewing tobacco sold in the United States and evoke plasma exudation from the oral mucosa," *Clinical Diagnostics Laboratory and Immunology*, vol. 9, pp. 1057–1060, 1992. View at Google Scholar

32. R. L. Barnes and S. A. Glantz, "Endotoxins in tobacco smoke: shifting tobacco industry positions," *Nicotine and Tobacco Research*, vol. 9, no. 10, pp. 995–1004, 2007. View at Publisher · View at Google Scholar · View at PubMed

33. A. Morin, F. Samson, A. Porter, and J. Torrie, "Development of an easy to-search database on the microbes associated with tobacco," 1990 Bates number 620693477/3480. Retrieved on Nov. 8, 2010 from http://tobaccodocuments.org/rjr/522305212-5212.html.

34. J. D. Hasday, R. Bascom, J. J. Costa, T. Fitzgerald, and W. Dubin, "Bacterial endotoxin is an active component of cigarette smoke," *Chest*, vol. 115, no. 3, pp. 829–835, 1999. View at Publisher · View at Google Scholar

35. K. S. Lane, "Method and system for assay and removal of harmful toxins during processing of tobacco products," US patent 6,786,221. September 7, 2004.

36. L. Larsson, B. Szponar, and C. Pehrson, "Tobacco smoking increases dramatically air concentrations of endotoxin," *Indoor Air*, vol. 14, no. 6, pp. 421–424, 2004. View at Publisher · View at Google Scholar · View at PubMed

37. W. P. Hempling, G. H. Bokelman, and M. Shulleeta, "Method for reduction of tobacco specific nitrosamines," US patent 6,755,200, June 29, 2004.

38. A. P. Rooney, J. L. Swezey, D. T. Wicklow, and M. J. McAtee, "Bacterial species diversity in cigarettes linked to an investigation of severe pneumonitis in U.S. military personnel deployed in Operation Iraqi Freedom," *Current Microbiology*, vol. 51, no. 1, pp. 46–52, 2005. View at Publisher · View at Google Scholar · View at PubMed

39. A. Sebastian, C. Pehrson, and L. Larsson, "Elevated concentrations of endotoxin in indoor air due to cigarette smoking," *Journal of Environmental Monitoring*, vol. 8, no. 5, pp. 519–522, 2006. View at Publisher · View at Google Scholar · View at PubMed

40. M. Zhao, B. Wang, F. Li et al., "Analysis of bacterial communities on aging flue-cured tobacco leaves by 16S rDNA PCR-DGGE technology," *Applied Microbiology and Biotechnology*, vol. 73, no. 6, pp. 1435–1440, 2007. View at Publisher · View at Google Scholar · View at PubMed

41. L. Larsson, B. Szponar, B. Ridha et al., "Identification of bacterial and fungal components in tobacco and tobacco smoke," *Tobacco Induced Diseases*, vol. 4, no. 4, 2008. View at Google Scholar

42. J. L. Pauly, J. D. Waight, and G. M. Paszkiewicz, "Tobacco flakes on cigarette filters grow bacteria: a potential health risk to the smoker?" *Tobacco Control*, vol. 17, supplement 1, pp. i49–i52, 2008. View at Google Scholar

43. J. Yang, J. Yang, Y. Duan et al., "Bacterial diversities on unaged and aging flue-cured tobacco leaves estimated by 16S rRNA sequence analysis," *Applied Microbiology and Biotechnology*, vol. 88, pp. 553–562, 2010. View at Google Scholar

44. L. M. Coussens and Z. Werb, "Inflammation and cancer," *Nature*, vol. 420, no. 6917, pp. 860–867, 2002. View at Publisher · View at Google Scholar · View at PubMed

45. O. Takeuchi and S. Akira, "Pattern recognition receptors and inflammation," *Cell*, vol. 140, no. 6, pp. 805–820, 2010. View at Publisher · View at Google Scholar · View at PubMed

46. M. Karin, T. Lawrence, and V. Nizet, "Innate immunity gone awry: linking microbial infections to chronic inflammation and cancer," *Cell*, vol. 124, no. 4, pp. 823–835, 2006. View at Publisher · View at Google Scholar · View at PubMed

47. C. Nathan and A. Ding, "Nonresolving inflammation," *Cell*, vol. 140, no. 6, pp. 871–882, 2010. View at Publisher · View at Google Scholar · View at PubMed

48. N. Azad, Y. Rojanasakul, and V. Vallyathan, "Inflammation and lung cancer: roles of reactive oxygen/nitrogen species," *Journal of Toxicology and Environmental Health B*, vol. 11, no. 1, pp. 1–15, 2008. View at Publisher · View at Google Scholar · View at PubMed

49. L. Zitvogel, O. Kepp, and G. Kroemer, "Decoding cell death signals in inflammation and immunity," *Cell*, vol. 140, no. 6, pp. 798–804, 2010. View at Publisher · View at Google Scholar · View at PubMed

50. K. E. de Visser and L. M. Coussens, "The inflammatory tumor microenvironment and its impact on cancer development," *Contributions to Microbiology*, vol. 13, pp. 118–137, 2006. View at Google Scholar

51. J. K. Kundu and Y. J. Surh, "Inflammation: gearing the journey to cancer," *Mutation Research*, vol. 659, no. 1-2, pp. 15–30, 2008. View at Publisher · View at Google Scholar · View at PubMed

52. E. A. Engles, "Inflammation in the development of lung cancer: epidemiological evidence," *Expert Review of Anticancer Therapy*, vol. 8, no. 4, pp. 605–615, 2008. View at Google Scholar

53. A. I. D'hulst, K. Y. Vermaelen, G. G. Brusselle, G. F. Joos, and R. A. Pauwels, "Time course of cigarette smoke-induced pulmonary inflammation in mice," *European Respiratory Journal*, vol. 26, no. 2, pp. 204–213, 2005. View at Publisher · View at Google Scholar · View at PubMed

54. C. Smith, T. Perfetti, and J. King, "Perspectives on pulmonary inflammation and lung cancer risk in cigarette smokers," *Inhalation Toxicology*, vol. 18, no. 9, pp. 667–677, 2006. View at Publisher · View at Google Scholar · View at PubMed

55. H. Van Der Vaart, D. S. Postma, W. Timens, and N. H. T. Ten Hacken, "Acute effects of cigarette smoke on inflammation and oxidative stress: a review," *Thorax*, vol. 59, no. 8, pp. 713–721, 2004. View at Publisher · View at Google Scholar · View at PubMed

56. M. A. Birrell, S. Wong, M. C. Catley, and M. G. Belvisi, "Impact of tobacco-smoke on key signaling pathways in the innate immune response in lung macrophages," *Journal of Cellular Physiology*, vol. 214, no. 1, pp. 27–37, 2008. View at Publisher · View at Google Scholar · View at PubMed

57. L. Sorokin, "The impact of the extracellular matrix on inflammation," *Nature Reviews Immunology*, vol. 10, no. 10, pp. 712–723, 2010. View at Google Scholar

58. W. Huvenne, C. A. Pérez-Novo, L. Derycke et al., "Different regulation of cigarette smoke induced inflammation in upper versus lower airways," *Respiratory Research*, vol. 11, no. 110, pp. 1–9, 2010. View at Google Scholar

59. G. S. Kulkarni, P. P. Nadkarni, J. M. Cerreta, S. Ma, and J. O. Cantor, "Short-term cigarette smoke exposure potentiates endotoxin-induced pulmonary inflammation," *Experimental Lung Research*, vol. 33, no. 1, pp. 1–13, 2007. View at Publisher · View at Google Scholar · View at PubMed

60. E. Doz, N. Noulin, E. Boichot et al., "Cigarette smoke-induced pulmonary inflammation is TLR4/MyD88 and IL-1R1/MyD88 signaling dependent," *Journal of Immunology*, vol. 180, no. 2, pp. 1169–1178, 2008. View at Google Scholar

61. M. R. Stämpfli and G. P. Anderson, "How cigarette smoke skews immune responses to promote infection, lung disease and cancer," *Nature Reviews Immunology*, vol. 9, no. 5, pp. 377–384, 2009. View at Publisher · View at Google Scholar · View at PubMed

62. H. Mehta, K. Nazzal, and R. T. Sadikot, "Cigarette smoking and innate immunity," *Inflammation Research*, vol. 57, no. 11, pp. 497–503, 2008. View at Publisher · View at Google Scholar · View at PubMed

63. M. Sopori, "Effects of cigarette smoke on the immune system," *Nature Reviews Immunology*, vol. 2, no. 5, pp. 372–377, 2002. View at Google Scholar

64. J. Domagala-Kulawik, "Effects of cigarette smoke on the lung and systemic immunity," *Journal of Physiology and Pharmacology*, vol. 59, no. 6, pp. 19–34, 2008. View at Google Scholar

65. D. G. Yanbaeva, M. A. Dentener, E. C. Creutzberg, G. Wesseling, and E. F. M. Wouters, "Systemic effects of smoking," *Chest*, vol. 131, no. 5, pp. 1557–1566, 2007. View at Publisher · View at Google Scholar · View at PubMed

66. D. Wood, "British-American Tobacco Company," Preliminary observations on the possible transfer of viable micro-organisms to mainstream smoke, 1968, Bates number 570343882/3901. Retrieved on June 24, 2011 from http://legacy.library.ucsf.edu/tid/jnd51f00.

67. J. Forgacs, Good Samaritan Hospital, Suffern, NY to Dr. Robert C. Hockett, Council for Tobacco Research, New York, NY, 2 pages, 2010, http://legacy.library.ucsf.edu/tid/ppd2aa00.

68. J. Forgacs, "Mycotoxicoses: the neglected diseases," *Feedstuffs*, vol. 36, no. 18, pp. 124–134, 1966. View at Google Scholar

69. B. Slutzker, G. Harmon, and P. Edmonds, "Microbiological content of tobacco smoke," *The American Journal of the Medical Sciences*, vol. 243, pp. 196–201, 1962. View at Google Scholar

70. J. M. Greene and S. Caldwell, "Chemical and microbiological changes during flue curing of NK-149 tobacco," 1989, R. J. Reynolds, Bates number 514848867/8887, retrieved on June 30, 2010 from http://legacy.library.ucsf.edu/tid/qlm03d00.

71. Anonymous, Brown & Williamson, "Package 13.0 microbiology," No date. Bates number 620648956/9146. Retrieved on June 28, 2010 from http://legacy.library.ucsf.edu/tid/key21f00.

72. Anonymous, British American Tobacco, "Master RD 888-R," Bates number 105597011/7062. Retrieved on December 11, 2009 from http://legacy.library.ucsf.edu/tid/unit 37a99.

73. C. W. Bacon, R. Wenger, and J. F. Bullock, "Chemical changes in tobacco during flu-curing," *Industrial & Engineering Chemistry*, vol. 44, no. 2, pp. 292–296, 1952. View at Google Scholar

74. C. O. Jensen, "Uber die natur der tabakfermentation," *Zentrabl Bakteriol Parasitenk, Abt II*, vol. 21, pp. 469–483, 1908. View at Google Scholar

75. W. P. Hempling and P. Morris, "Fundamental tobacco microbiology," 1987. Bates number 2022226783/6795. Retrieved on March 24, 2010 from http://legacy.library.ucsf.edu/tid/jst58e00.

76. K. J. Brotzge and Brown and Williamson Tobacco Company, Quantities of microflora recovered from Brown & Williamson & competitive cigarette brands, Fall/Winter, 1982, 1983. Bates number 598000442/0451. Retrieved on March 16, 2010 from http://tobaccodocuments.org/bw/971381.html.

77. K. J. Brotzge and Brown & Williamson Tobacco Company, "Quantities of microflora recovered from Brown & Williamson and competitive brands, Spring/Summer 830000," 1983, Bates number 657017733/7752. Retrieved on March 16, 2010 from http://legacy.library.ucsf.edu/tid/hnl13f00.

78. L. J. Dewey and G. M. Broaddus, "Bacterial, mold and yeast population counts on RCFS and on RC picked from Pall Mall and Winston cigarettes," 1970, American Tobacco Company, Bates number 950107079/7080, Retrieved on March 16, 2010 from http://legacy.library.ucsf.edu/tid/jml11a00.

79. J. Hill and Brown & Williamson, "Microflora standards of cocoa casing materials," 1985. Bates number 62018442/4422. Retrieved on March 17, 2010 from http://legacy.library.ucsf.edu/tid/ski31f00.

80. M. I. Hofer and Philip Morris, "Research and development—quarterly Report Microbiology 851000/1200," 1985, Bates number 2028639252/9269. Retrieved on November 8, 2010 from http://legacy.library.ucsf.edu/tid/rew56e00.

81. Philip Morris, "Biocontrol of tobacco microflora," 1989, Bates number 2029139024/9050, retrieved on June 30, 2010 from http://legacy.library.ucsf.edu/tid/hoy69e00.

82. R. E. Welty and American Tobacco, "Plant pathology, 5225, microflora of flue-cured tobacco and their affect on quality," 1970, Bates number 950251672/1675. Retrieved on June 30, 2010 from http://legacy.library.ucsf.edu/tid/ufv31A00.

83. Anonymous and Philip Morris, "Most populous bacteria: burley tobacco research," 1999, Bates number 2082730005. Retrieved on March 19, 2010 from http://legacy.library.ucsf.edu/tid/ddq55c00.

84. Anonymous, "Further examination of coliform bacteria from cigarettes," Laboratory report L.337-R. 1970, Bates number 650018029/8046. Retrieved on June 24, 2010 from http://legacy.library.ucsf.edu/tid/rkl66b00.

85. M. Di Giacomo, M. Paolino, D. Silvestro et al., "Microbial community structure and dynamics of dark fire-cured tobacco fermentation," *Applied and Environmental Microbiology*, vol. 73, no. 3, pp. 825–837, 2007. View at Publisher · View at Google Scholar · View at PubMed

86. T. G. Mitchell and British American Tobacco (BAT), "Changes in the microflora of tobacco leaves during field growth in England," 1989, Bates number 400047269/7282, retrieved on June 28, 2010 from http://legacy.library.ucsf.edu/tid/num81a99.

87. S. A. Ghabrial, "Studies on the microflora of air-cured burly tobacco," *Tobacco Science*, vol. 20, pp. 80–82, 1976. View at Google Scholar

88. British American Tobacco, "Film Box Number -1, L1R to L151 R, R&D 1838," Bates number 402185400/5586, Retrieved on June 24, 2010 from http://legacy.library.ucsf.edu/tid/fud91a99.

89. W. C. Squires, L. E. Hayes, and R. J. Reynolds, "Tobacco flora: quantitative studies," November 9, 1961. 125 pages/ Retrieved on October 27, 2010 from http://tobaccodocuments.org/rjr/500937365-7489.html.

90. V. Subbiah, "Sheet2. Tobacco sampling for microflora counting," 1995. Bates number 525450330/0335. Retrieved on October 22, 2010 from http://legacy.library.ucsf.edu/tid/ymt60d00.

91. W. C. Flanders, R. J. Reynolds, "Quantitative studies of the microbiological flora of tobacco during aging," 1955. Bates number 501663388/3456. Retrieved on July 1, 2010 from http://legacy.library.ucsf.edu/tid/wuk39d00.

92. P. C. Stauber, "Investigation of mould growth on stored leaf," 1975. Bates number 105425004/5072. Retrieved on June 24, 2011 from http://legacy.library.ucsf.edu/tid/oit57a99.

93. R. E. Welty and L. A. Nelson, "Growth of aspergillus repens in flue-cured tobacco," *Applied Microbiology*, vol. 21, no. 5, pp. 854–859, 1971. View at Google Scholar

94. T. G. Mitchell, D. A. Johnson, and British-American Tobacco Company, "Identification of fungi of the Aspergillus flavour group from tobacco," Report RD 1279. 1975. Bates number 105598328/8619. Retrieved on July 1, 2010 from http://library/ucsf/edu/tid/pnp57a99.

95. G. M. Myers, "Aflatoxin on tobacco and its removal," R. J. Reynolds, Bates number 519972600/2620. Retrieved on June 29, 2010 from http://legacy.library.ucsf.edu/tid/yjk90d00.

96. J. M. Greene and S. Caldwell, "Chemical and microbiological changes during flue curing of NK-149 tobacco," 1989, R. J. Reynolds, Bates number514848867/8887, Retrieved on June 30, 2010 from http://legacy.library.ucsf.edu/tid/qlm03d00.

97. D. G. Vickroy and R. E. Welty, "Evaluations of cigarettes made with mold-damaged and nondamaged flue-cured tobacco," *Beiträge zur Tabakforschung*, vol. 8, pp. 102–106, 1975. View at Google Scholar

98. M. R. Tansey, "Isolation of thermophilic fungi from snuff," *Journal of Applied Microbiology*, vol. 29, no. 1, pp. 128–129, 1975. View at Google Scholar

99. T. Thomas, J. Brandon, W. A. Bailey, and T. A. Kosty, "Method for reducing nitrosamines in tobacco," US patent 7,757,697. July 20, 2010.

100. A. Lukic, R. E. Welty, and G. B. Lucas, "Antifungal spectra of actinomycetes isolated from tobacco," *Antimicrobial Agents and Chemotherapy*, vol. 1, no. 4, pp. 363–366, 1972. View at Google Scholar

101. K. Koga, S. Katsuya, and Japan Tobacco Company, "Method of reducing nitrosamines content in tobacco leaves," US ptent 7,556,046. July 7, 2009.

102. M. Cui, M. T. Nielsen, R. R. Hart III, M. L. Overbey, D. J. Watson, and J. R. Chipley, "Use of chlorate, sulfur or ozone to reduce tobacco specific nitrosamine," U.S. patent 2006/019516 A1. Sept 7, 2006.

103. R. G. Warke, A. S. Kamat, and M. Y. Kamat, "Irradiation of chewable tobacco mixes for improvement in microbiological quality," *Journal of Food Protection*, vol. 62, no. 6, pp. 678–681, 1999. View at Google Scholar

104. T. G. Mitchell and C. R. Jenkins, "Alternative treatments for mould control on pipe tobacco," British American Tobacco, Bates number 400661432/1433. Retrieved on June 24, 2011 from http://legacy.library.ucsf.edu/tid/rir56a99.

105. D. S. Roth, W. H. Cowart Jr., C. B. Jenkins Jr., and D. M. Boyle, "Sterilization process in the manufacturing of snuff," U.S. patent 5,372,149. December 13, 1994.

106. V. Subbiah, "Method of inhibiting mycotoxin production," US Patent 5,698,599. Dec 16, 1997.

107. R. P. Newton and Brown & Williamson, "Microbiological examination of cigarettes," 1968. Retrieved on June 28, 2010 from http://legacy.library.ucsf.edu/tid/vgj94a99.

108. V. C. Johnson, A. M. Palmer, and P. Morris, "Bacteria on cigarette filters," Bates number 2000759148. February 12, 1968. Retrieved on November 9, 2010 from http://legacy.library.ucsf.edu/tid/aiw48e00.

109. T. G. Mitchell and British-American Tobacco Company, "Examination of mould—Affected cigarettes from China," 1989, Bates number 400910779/7783. Retrieved on June 24, 2010 from Legacy at http://legacy.library.ucsf.edu/tid/qvu0499.

110. J. Hill and Brown & Williamson, "Microbial examination of pipe and smokeless tobacco/541," 1985, Bates number 620184560/4571. Retrieved on July 22, 2010 from http://legacy.library.ucsf.edu/tid/rjq20f00.

111. K. Brotzge and Brown & Williamson, "Microbial examination of pipe, snuff, & chewing tobacco products—Fall/Winter, 83000," 1984, Bates number 598002147/2156. Retrieved on June 24, 2011 from http://legacy.library.ucsf.edu/tid/zcj41f00.

112. S. K. Varma, A. B. Roy, and A. K. Jha, "Ecotoxicological aspects of Aspergilli present in the phylloplane of shored leaves of chewing tobacco (Nicotiana tobacum)," *Mycopathologia*, vol. 113, pp. 19–23, 1991. View at Google Scholar

113. A. R. Sapkota, S. Berger, and T. M. Vogel, "Human pathogens abundant in the bacterial metagenome of cigarettes," *Environmental Health Perspectives*, vol. 118, no. 3, pp. 351–356, 2010. View at Publisher · View at Google Scholar · View at PubMed

114. J. Papavassiliou, G. Piperakis, and U. Marcelou-Kinti, "Mycological flora of cigarettes," *Mycopathology Mycology Applied*, vol. 44, no. 2, pp. 117–120, 1971. View at Google Scholar

115. V. P. Kurup, A. Resnick, S. L. Kagen, S. H. Cohen, and J. N. Fink, "Allergenic fungi and actinomycetes in smoking materials and their health implications," *Mycopathologica*, vol. 82, no. 1, pp. 61–64, 1983. View at Google Scholar

116. P. E. Verweij, J. J. Kerremans, A. Voss, and J. F. G. M. Meis, "Fungal contamination of tobacco and marijuana," *Journal of the American Medical Association*, vol. 284, no. 22, p. 2875, 2000. View at Google Scholar

117. N. B. Rainer, "Cigarettes having minimized loose ends and process for preparing same," US patent 4,715,388, Dec 29, 1987.

118. British American Tobacco Company, "Discussion group on ends quality," 1985, 161 pages, http://tobaccodocuments.org/batco/109979765-9924.html.

119. L. Deyton, J. Sharfstein, and M. Hamburg, "Tobacco product regulation—a public health approach," *The New England Journal of Medicine*, vol. 362, no. 19, pp. 1753–1756, 2010. View at Publisher · View at Google Scholar · View at PubMed · View at Scopus

EXHIBIT 6

From: Dominik Skulec
To: Public Health Rules
Subject: Comment on recent changes to testing legislation
Date: Thursday, February 17, 2022 8:00:10 AM

I want to express my dissatisfaction with the new rules, they hugely disadvantage small growers which I wholeheartedly support. I back Jason Lampman from State 3 and believe he knows what's best for small growers. These new proposals are not good!

EXHIBIT 7

From: Hopeful Producer
To: Public Health Rules
Subject: OHA Hearing on Cannabis testing & lab accreditation standards written comments
Date: Sunday, February 20, 2022 4:41:45 PM

Hello,

I agree the new definition of a harvest lot being expanded from 72 hours to a week will help small micro-tier producers save money and time. However, the expanded 50 pound batch size for testing will not help the producers that are so small that they cannot reach that limit on a single harvest lot.

I'm not sure how to help those small producers but they are already being pressured financially from factors making Oregon a hard place for actual Oregonian Cannabis companies to survive.

EXHIBIT 8

From: jenilynn monfrey
To: Public Health Rules
Subject: Proposed laboratory testing requirements re heavy metals, etc.
Date: Monday, February 21, 2022 12:38:56 PM

We are a micro tier 1 producer and would like to comment on this proposed rule:

We object to adding these additional tests and requiring the labs to purchase several thousand dollars worth of new equipment, thereby having to raise the costs of full compliance test to the producers. This rule is unfair to any producer not able to have a 100 pound harvest. Only large producers can ever have 100 pounds of harvest, which is one reason OLCC thinks it offsets this new lab cost. A producer that has a 3 to 15 pound harvest really cannot afford higher lab costs.

I hope this comment is helpful for your decision-making on this rule.

Thank you,
Jenilynn Monfrey
Limpy Creek Cannabis, LLC

EXHIBIT 9

From: L A
To: Public Health Rules; Charlie Bennett; kiwi@sterileaf.com; steve@sterileaf.com
Subject: Public Comments regarding Draft Rules
Date: Monday, February 21, 2022 4:41:21 PM

To Whom it May Concern,

I am writing today to express my extreme concern for the lack of testing that will be taking place in regards to molds and mycotoxins in cannabis. I am glad to see the advancement for testing of Mycotoxins but Mold should also be counted. I inquired as to "why" the OHA has chosen to forgo this testing and the reply I was told is without merit, Science, or any studies supporting the explanation;
"OHA is not proposing to adopt rules for testing total yeast and mold as a microbiological test since it is just a presence absence test for any type of yeast or mold. There are some forms of yeast that are used in the cultivation process that are not harmful and could cause a batch of marijuana to fail when there aren't any harmful organisms on the plant. From talking to other states they indicated to us that this is not an effective test and that many would be reconsidering requiring this test in the future. It should be noted that not all states with legal marijuana require testing for total yeast and mold. OHA has chosen to focus microbiological testing on organisms, like the four Aspergillus species, Shiga toxin-producing E. coli and Salmonella, that are harmful if ingested in any form".

My question is this: Where is the Science on this? Where are the research papers stating this is true? Where is the data on this study? Is this just yeast? What mold does harm humans? Is this mold found in Cannabis?

I chose to do my own study on shelved cannabis Feb. 2022 and my results showed 60% of them were over 40,000 cfu/g and as high as 800,000 cfu/g. This is astronomically high and an absolute human health risk for inhalation, ingestion, & topical applications with several studies backing up these findings.
The mold counts were so high they could not count the yeast; the mold covered the plate. Imagine what that is doing to someone who inhales contaminated cannabis full of microbials.

I do not understand how an organization in charge of Consumer Health & Protection can bypass the presence of mold so high that it is beyond USDA & FDA acceptable levels for human consumption. Science has proven inhalation of any mold is detrimental to human health. 13 other states recognize thresholds in line with the FDA at 10,000cfu/g. At 100,000 cfu/g the USDA & the FDA declares any Dairy, Food, Pharma, or other products unfit for human consumption. How is mold in cannabis any different? It is a plant. Even tobacco, another inhalable plant has the same limits.

The fact the OHA is not even acknowledging this issue is absurd and will carry grave risks for consumers, especially those who have mold toxicity; making inhalation, ingestion or topical application of contaminated products a life threatening health risk.

For those who have a compromised immune system this can be fatal causing MCAS (Mast Cell Activation Syndrome), Allergic Anaphylaxis, Headache, Nausea and other unexplained reactions. There is a recent article out today (Frightening & mysterious illness affects some regular marijuana users) questioning why cannabis is making people sick; my thought is mold contamination is so high it is toxic to the body and causing unexplained toxic effects because most Doctors do not understand the scope of mold poisoning. Can we afford to put human health at risk again before knowing the full spectrum of the issue? Recent surveys of cannabis products determined the presence of over 4,000 different fungal taxonomic classifications in cannabis flower, including several pathogenic fungal agents. This will be another Vape Gate inhalation crisis, one that can and should be avoided by adopting strict mold count thresholds to be at or below 10,000 cfu/g as seen by 13 other states including Colorado.

The OHA should not be risking the public and human health without backing up their findings with Science based evidence that mold does not affect human health.

The OHA has failed to provide Science to back up their claims, even stating in their own technical report they “do not have enough data” to be completely sure of anything and so they default to some other form of acceptable limits is unacceptable.

The OHA needs to prove without a doubt these limits are acceptable for human consumption. With “scant research” in existence and the fact the AOAC body they are following for testing standards is still writing the: “Methods Committee Guidelines for Validation of Microbiological Methods for Cannabis and Cannabis Products”.

It is my opinion Oregon should be at the forefront of consumer health and protection. Consumer health and safety should be addressed with limits that have been thoroughly studied and already set by the FDA & USDA regarding mold counts in the food supply and pharmacopeia. The OHA should be required to prove TYM counts do not affect human health. They should not be allowed to pick & choose which data & research they want to apply to their rule making and disregard the science of others or lack thereof.

The OHA has no reference lab, no money or intention to set one up. They do not have a plan, an audit system to track the data or any Scientific research to back up their findings or statements. If they stand for Consumer Health & Protection why are they not testing more thoroughly? The OHA clearly stated TYM is “only an indication of yeast & mold” which DOES Present a Human Health Risk as stated by the Federal Government.
Oregon should be setting the right standards in anticipation of Federal Legalization as they have already taken the steps with Export laws now in place. The FDA will require these strict testing protocols and Oregon should be ready. I urge the OHA to reconsider their testing protocols and the risk mold has on human health, especially in cannabis. These products have been proven to help ailments, but they are detrimental if contaminated. Testing for Mycotoxins alone does not go far enough to ensure the safety consumers deserve from the other unknown microbial growth they will inhale, ingest, or apply topically.

Respectfully,

Laurie Andrade

EXHIBIT 10

From: Susan Sheythe
To: Public Health Rules
Subject: New Cannabis regulations
Date: Tuesday, February 15, 2022 7:47:40 PM

Hello,

Sure wish cannabis and alcohol were separate.

We need some kind of state bank we can use for the tax money from cannabis sales to go; and also medical cannabis users need to be able to report costs of medical cannabis on state income taxes as a deduction along with other medical not reimbursed.

Recreational and medical cannabis needs to be separated in different buildings or sections of buildings so that rising prices for recreational doesn't automatically increase price of medical marijuana, neither of which is reimbursed by medical insurance.

Finally and most importantly, medical cannabis needs to be organic (actually all of cannabis, both recreational and medical should be organic). It would
need to not be treated with poisons to prevent the plants from infestations of mites or molds. These issues make the cannabis unusable as a smoke or edible, esp, if lung or breathing issues are present.

Lp

EXHIBIT 11

PathogenDx
Setting the standard in DNA testing

Comments on Proposed Updates to Chapter 333, Division 7

OMMP and ORELAP

Submitted by:
Milan Patel, Founder & CEO
PathogenDx

Thank you for your continued work on these important regulations, which have improved significantly since we filed comments on the earlier draft in November 2021. For example, the addition of testing for pathogenic E.coli and Salmonella was very welcome, as both of these contaminants can be seriously harmful to patients and are tested for in nearly every other regulated marijuana program.

We also appreciate the modification of 333-007-390 to allow for alternate DNA-based methods in addition to qPCR, as there are multiple alternative systems — including our own — which can produce the same results more cost-effectively. However, we do have one remaining recommendation to improve these regulations even further, as the current draft still requires enrichment. Enrichment is typically necessary for qPCR, but is not always required for alternate DNA-based methods (digital drop -PCR, Sequencing, DNA Microarray etc).

Recommendation:

Modify the new Aspergillus testing standards to remove the requirement for enrichment, as long as a testing method has been certified by an independent scientific body (such as the AOAC) and validated at an independent test lab to not require it, and the candidate Alternate DNA method shows equivalency to the reference method (plate culture) in terms of fractional recovery, and no statistically significant difference between the two methods.

Suggested language:

Modify 333-007-0390: Standards for Microbiological Contaminants Compliance Testing as follows:

333-007-0390
Standards for Microbiological Contaminants Compliance Testing
…
(3) Aspergillus speciation testing shall be performed using either:
(a) a qPCR analysis ~~or alternate DNA-based method~~ on sample material that has been enriched in fungus-specific media for a minimum of 48 hours~~.~~; or
(b) an alternate DNA-based method that does not require enrichment that has been certified by an independent scientific body such as the AOAC, and that shows

equivalency in terms of fractional recovery and no statistically significant difference between the alternate DNA-based method and a reference method such as plate culture requiring enrichment.

Reasoning:

Enrichment is necessary for many testing methods, but not for all of them. For example, our system is able to detect contaminants to the same standard without the need for enrichment, and is already operational in multiple cannabis testing programs throughout the country.

We believe that the requirement for enrichment in regulation would result in false negatives if the exact enrichment media, temperature and time conditions are not used, and applied correctly. Most of the enrichment media currently used in cannabis microbial testing is resulting in non-specific bias enrichment where the background microflora is promoted resulting in incorrect results. Such a requirement would also discourage the creation of other new testing methods that can achieve comparable results more efficiently, while making these regulations enrichment-neutral would allow for innovations that lower costs for operators and patients alike.

In order to ensure that methods that don't use enrichment are achieving the same results as those that do enrich, we proposed referencing an external source like the AOAC PTM certifications conducted at an independent lab. Certifications from the AOAC specify the procedures for each method, so only methods that have been certified by the AOAC to not need enrichment would be able to skip this step, while those that do need enrichment would still need to perform it as specified in their procedures.

Conclusion:

Thank you again for your work, and for your consideration of our input. Please do not hesitate to contact us if you have any questions or would like additional information.

Milan Patel
Founder & CEO
PathogenDx
https://pathogendx.com/

PathogenDx's mission: To become the industry standard for DNA-based microbial testing technology in the cannabis, agriculture, food and beverage industries, promoting growing businesses, safer products and healthier lives.

EXHIBIT 12

From: Sun God Meds
To: Public Health Rules; Quality Assurance
Subject: Comments on proposed permanent rulemaking – OAR chapter 333, divisions 7 and 64
Date: Monday, February 21, 2022 4:50:35 PM

Re: Comments for the public record and consideration on : "Marijuana and hemp testing and laboratory accreditation standards"

To whom it may concern,

My name is Naomi and I am the Quality Manager at Sun God Medicinals, a subsidiary of Sun Breeze Incorporated, a small seed-to-sale cannabis business. We are also licensed to produce hemp products for sale in both Oregon and the general market. We have reviewed the new OHA proposed rules for marijuana and hemp testing and laboratory accreditation standards. Below are the comments we would like to submit regarding the proposed rules.

We appreciate and respect that OHA has identified issues and has taken action to further ensure the safety of cannabis and hemp consumers. However, we do not agree that these changes will have a limited financial impact; we believe that these changes will have an enormous financial impact to producers, processors, labs, and eventually to consumers. We believe the proposed changes have been introduced at a time when the industry is already heavily burdened by the fall out of Covid-19, supply shortages, rising inflation, and declining cannabis and hemp prices. We feel that the impact of these changes would be so financially burdensome, that processors, producers, and consumers will turn to the illicit market, further crippling our struggling legal market.

We understand and agree that additional testing is needed to ensure the safety of the products entering the market. We do not agree, however, that the elimination of Control Studies will further the cause of consumer safety.

For the purpose of this comment, an example of our current product will be used. We manufacture infused pre-rolls in 1,000 unit batches. We make 8 varieties of these pre-rolls under one control study that is valid for 2 years. In those two years, we may make (4) 1000 unit batches of each variety for a total of 32 batches. The current cost to run a control study for these products is approximately $1600. Under this control study, to test 32 batches will cost $4480. In total, the price for testing will be $6080 ($0.19 per unit). This will result in an extremely burdensome fiscal impact to our company and many others.

Under the proposed rules, if we make (32) 1000 unit batches that each have to be tested, 6 samples of each batch will need to be taken. Using the estimated cost per sample provided in the proposed rules, the testing of 32 batches will cost anywhere from $69,000 to $82,000. That is a $60,000+ increase in testing costs just over a two year period, a $0.31 increase per unit. We strongly advocate to keep Control Studies as an acceptable sampling and testing method as there is insufficient evidence that Control Studies have a negative impact on the safety of consumers. If Control Studies cannot be kept, we ask that current control studies be honored until their expiry date.

While the proposed rules state that the financial impact of these rules will be minimal to producers and processors, we strongly disagree. Sampling costs are not going to decrease with these rule changes because the laboratories are going to have to increase prices to pay for the equipment and accreditation to comply with these rules. These costs will be passed on to producers and processors

as more samples are required, more labor, time and mileage, and sampling fees are going to be required. And eventually those costs are going to be passed down to retailers and consumers.

We would also like to advocate for clearer guidance regarding homogenization of samples. As a seed-to-sale company, we need to know the methods that our laboratory partners adhere to, especially if we use more than one laboratory for testing. It is unclear in these rules as to where the homogenization should take place – should it take place in the field by the sampler or at the lab by a trained technician? Furthermore, many cannabinoid products are difficult to work with, e.g. distillates, live resins, and crude oils are like working with cold molasses. The homogenization of sample increments of these products will be very difficult to achieve without heating or diluting, both of which can alter test results. We find that there will be an increase in failed tests, loss of product, additional testing costs, and inaccurate results as it will be even more difficult to achieve a 10% RPD between samples with unclear homogenization methods.

Thank you for the opportunity to comment on these rules and for your time and consideration in reading our comments. We trust that our comments, as well as others submitted by our peers in the industry, will be carefully considered.

Naomi Carbone
Sun God Medicinals
Herbal Infused Products
Phone: 541-423-8080
Facebook | Instagram | Twitter
OLCC Division - Sun God Medicinals LLC
Central Point OR 97502 • 540 E Vilas Rd Suite C
OLCC #10037523839 • www.sungodmeds.com

EXHIBIT 13

From: Robert Thomas
To: Farrer David G; David.G.Farrer@state.or.us; Public Health Rules
Cc: Hamade Ali K; FLERCHINGER Margaret; Robert Thomas
Subject: Re: Heavy metal action limits
Date: Thursday, February 10, 2022 7:13:39 AM

Thank you for you quick response David. I encourage you all to read my white paper, which will give you a much better understanding of the sources of elemental contaminants in the life cycle of medicinal and consumer cannabis products. As a point of reference, the pharmaceutical industry regulates up to 24 elemental impurities (Pb, Cd, As, Hg, Co,V, Ni, Tl, Au, Pd, Ir, Os, Rh, Ru, Se, Ag, Pt, Li, Sb, Ba, Mo, Cu, Sn, Cr) in drug products, based on classification of toxicity and the likely risk of finding them somewhere in the manufacturing process.

On the state side, New York regulates, Pb, Cd, As, Hg, Cr, Zn, Cu, Ni, Sb, while Michigan includes Pb, Cd, Inorganic As, Hg, Cr, Cu, Ni. Maryland and a few other states includes Pb, Cd, As, Hg and Cr. Moreover, the National Institute of Standards and Technology (NIST), the premier producer of reference standards, has just developed a 13 toxic element certified reference material (CRM), which includes, Pd, Cd, As, Hg, Be, Co, Cr, Mn, Mo, Ni, Se, U, and V. In addition, I serve of the ASTM D-37 standards committee and we are in the process of writing an ICP-MS method for measuring up to 20 elemental contaminants in cannabis and hemp. It's also worth emphasizing that Epidiolex, the only CBD-based drug sold in the US had to show compliance when it was approved by the FDA in 2018 by meeting permitted daily exposure (PDE) limits for 14 elemental impurities, Pb, Cd, As, Hg, Co,V, Ni, Li, Sb, Ba, Mo, Cu, Sn, Cr.

The point I'm making is that the cannabis industry is moving towards regulating an expanded panel of elemental contaminants as federal oversight will soon become a realty. I strongly encourage you to take this into consideration as you set the regulatory framework for regulating heavy metal contaminants in your state to ensure consumer safety.

I welcome the opportunity to answer your questions.

Best regards,

Rob

Robert Thomas, CSci, CChem, FRSC
Author of Measuring Heavy Metal Contaminants in Cannabis and Hemp
(https://www.routledge.com/Measuring-Heavy-Metal-Contaminants-in-Cannabis-and-Hemp/Thomas/p/book/9780367417376)
Principal Consultant
Scientific Solutions: Serving the Educational Needs of the Trace Element User Community
4615 Sundown Road
Gaithersburg, MD 20882
Office: 301-570-2811
Cell: 301-717-0900
Fax: 301-570-2811

Email: robert.james.thomas@verizon.net
Website: www.scientificsolutions1.com

On 2/9/2022 6:17 PM, Farrer David G wrote:

> Robert,
>
> Thank you for the information. I'm looping in some additional folks that work on rules related to testing in cannabis.
>
> David Farrer
> Toxicologist
> Oregon Health Authority
> 971-352-5663
>
> **From:** Robert Thomas <robert.james.thomas@verizon.net>
> **Sent:** Wednesday, February 9, 2022 1:09 PM
> **To:** David.G.Farrer@state.or.us; Public Health Rules <PublicHealth.Rules@dhsoha.state.or.us>; Robert Thomas <robert.james.thomas@verizon.net>
> **Subject:** Heavy metal action limits
>
>
>
> Hello David,
>
> Allow me to introduce myself. My name is Robert Thomas and I've worked in the field of trace element analysis and heavy metal toxicity for almost 50 years. A colleague of mine who works for a cannabis testing lab in Oregon recently sent me the Notice of Proposed Rulemaking for Marijuana and hemp testing and laboratory accreditation standards (at the link below).
>
> https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/CHRONICDISEASE/MEDICALMARIJUANAPROGRAM/Documents/rules/333-007_064-Notice_of_Proposed_Rulemaking_01_09_2022.pdf
>
> I'm writing to inform you that I believe the Oregon action limits for heavy metals and the way they are defined are inadequate. I've supported the educational needs of the medical cannabis community in the field of heavy metal testing for the past three years and based on compelling evidence in the open literature, you should be defining an expanded panel of elemental contaminants, which are toxicologically relevant to the cultivation, extraction, processing, packaging and delivery of medicinal cannabinoids, based on their

method of administration (oral, inhalation and transdermal). I have written many publications on this topic and include a white paper for your information and consideration (link below).

https://cdn.technologynetworks.com/ac/Resources/pdf/the-importance-of-measuring-heavy-metal-contaminants-in-cannabis-and-hemp-312957.pdf

Many states are re-assessing their regulatory limits and expanding the list to include additional heavy metals, in order to ensure consumer safety.

Gladly chat to you if you are interested in discussing further.

Best, Rob

--
Robert Thomas, CSci, CChem, FRSC
Author of Measuring Heavy Metal Contaminants in Cannabis and Hemp
(https://www.routledge.com/Measuring-Heavy-Metal-Contaminants-in-Cannabis-and-Hemp/Thomas/p/book/9780367417376)
_____
Principal Consultant
Scientific Solutions: Serving the Educational Needs of the Trace Element User Community
4615 Sundown Road
Gaithersburg, MD 20882
Office: 301-570-2811
Cell: 301-717-0900
Fax: 301-570-2811

Email: robert.james.thomas@verizon.net
Website: www.scientificsolutions1.com

EXHIBIT 14

Oregon Health Authority
Public Health Division

RE: Notice of Proposed Rulemaking
Chapter 333: Marijuana and hemp testing laboratory accreditation standards

Green Leaf Lab was founded in 2011 and is Oregon's longest operational cannabis testing laboratory. We are also the first cannabis testing laboratory in the nation to be state licensed and accredited. Green Leaf Lab is a small business and is minority and certified woman owned by Women's Business Enterprise National Council (WBENC). It is our understanding that Green Leaf Lab may be the only minority and woman owned cannabis and hemp testing laboratory in the state, creating diversity in Oregon's cannabis testing laboratories.

Green Leaf Lab has been asked to participate in numerous Oregon state Rules Advisory Committees (RACs) in the past, involving testing and consumer safety, such as the medical marijuana and recreational cannabis RAC (Rules Advisory Committee); the technical advisory RAC; the sampling RAC; and the Franwell METRC seed to sale RAC. We are committed to the overall success of Oregon's cannabis and hemp industry while focusing on a long-term business approach that promotes public health and safety.

Please see our comments regarding proposed rules below:

The Statement identifying how adoption of the proposed rules will effect racial equity in Oregon only looked at impact to certain OLCC licensees. It did not include impacts to testing laboratories. ORS 183.335(b)(F) requires a full statement of impacts to racial equity.

The Statement of fiscal and economic impact failed to adequately address and report the full description of reporting, recordkeeping, and administrative activities required to comply with the proposed rules. Further, they failed to include true cost of equipment, supplies, labor, and increased administration required to comply with the rule. This oversight violates ORS 183.336. The requirement for a complete cost of compliance effect on small businesses. See also OAR 137-001-0018.

<u>OAR 333-007-0440. Control Study [Proposed to Repeal]</u>

The proposed rule lacks a specified implementation date. Allowing the Oregon Health Authority (OHA) to set implementation dates without public input and a hearing fails any test for transparency in rule making and appears to violate OAR 137-003-0007. See also ORS 183.333 and 183.341. Not including a specified implementation date in the proposed rule is unclear and is not transparent. Requiring rule changes that reduce laboratory revenue and increase laboratory costs without any specified time or insufficient time to implement is burdensome and creates a substantial hardship on small minority and women owned laboratories. The steps involved in implementing these proposed changes are substantial as they require multiple workflow updates, such as but not limited to, re-writing standard operating procedures, documentation updates, software updates, and substantive staff training. Due to the global

pandemic, we have experienced a delay in vendor support due to vendor staffing issues. Both vendor support and employee staff time are required to implement these proposed changes.

To comply with state mandated control study testing rules in Oregon in 2016, Green Leaf Lab purchased additional instrumentation to ensure sufficient capacity. That instrumentation cost hundreds of thousands of dollars and will no longer be required under these new rules. This is an additional cost burden being placed on laboratories that was not addressed by the Oregon Health Authority (OHA). This cost burden is compounded by the revenue loss associated with the elimination of control studies.

The lack of a specified implementation date adds to the uncertainty around testing requirements for all licensees and makes it impossible for a business to plan and budget. We request the OHA require a October 1, 2022, effective date for the elimination of control studies. This is before the fall harvest and will allow sufficient time to address required resources for the decrease in revenue.

OAR 333-007-0360, Exhibit B, Table 7 [Updated sampling increment requirements for extract/concentrate/inhalable product testing]

The proposed rule lacks a specified implementation date. Allowing the Oregon Health Authority (OHA) to set implementation dates without public input and a hearing fails any test for transparency in rule making and appears to violate OAR 137-003-0007. See also ORS 183.333 and 183.341. Not including a specified implementation date in the proposed rule is unclear and is not transparent. Requiring rule changes that increase laboratory costs without any specified time or insufficient time to implement is burdensome and creates a substantial hardship on small minority and women owned laboratories. The steps involved in implementing these proposed changes are substantial as they require multiple workflow updates, such as but not limited to, re-writing standard operating procedures, documentation updates, software updates, and substantive staff training. Due to the global pandemic, we have experienced a delay in vendor support due to vendor staffing issues. Both vendor support and employee staff time are required to implement these proposed changes.

These new sampling rules create an additional cost burden on the laboratory due to the steps required for implementation, complexity in execution and continued compliance. Complexity opens the door to misinterpretation, which makes it more difficult and costly to manage and train. In addition to the laboratory burden, this complexity will make it more difficult for regulatory enforcement. Changing the replicate sample analysis to require compliance testing, instead of just solvents and potency, ensures accuracy in large production batches and reduces the complexity for reporting to METRC and issuing COA (Certificate of Analysis).

The lack of a specified implementation date adds to the uncertainty around testing requirements for all licensees and makes it impossible for a business to plan and budget. We request the OHA require an October 1, 2022, effective date for the new sampling requirements. This will allow sufficient time to make all the necessary changes and manage the additional cost burden for laboratories.

OAR 333-064-0100(2)(g). Cannabis Sampling Procedures and Testing. “Sample replicate analysis...”

The proposed rule lacks a specified implementation date. Allowing the Oregon Health Authority (OHA) to set implementation dates without public input and a hearing fails any test for transparency in rule making and appears to violate OAR 137-003-0007. See also ORS 183.333 and 183.341. Not including a specified implementation date in the proposed rule is unclear and is not transparent. Requiring rule changes that increase laboratory costs without any specified time or insufficient time to implement is burdensome and creates a substantial hardship on small minority and women owned laboratories. The steps involved in implementing these proposed changes are substantial as they require multiple workflow updates, such as but not limited to, re-writing standard operating procedures, documentation updates, software updates, and substantive staff training. Due to the global pandemic, we have experienced a delay in vendor support due to vendor staffing issues. Both vendor support and employee staff time are required to implement these proposed changes.

The proposed rule does not require full compliance of the replicate sample. The current proposed replicate analysis does not fully address the concerns of variability that occurs in large production batch sizes of extracts. Residual solvents, pesticides and potency can vary in large production batches and are often found concentrated in “pockets.” Having the replicate sample tested for all compliance tests would ensure large production batches have consistent potency results and ensure harmful contaminants such as pesticides, mycotoxins, heavy metals, microbial contaminants, and residual solvents are properly detected and ensure public health and safety is protected.

As proposed, the replicate samples create an undue burden for laboratories by increasing the complexity in issuing averaged results between primary and duplicate samples. With pass/fail residual solvent and %RSD (Relative Standard Deviation) on solvents required on replicate samples, plus averaged potency analysis, reporting would be unable to be performed via an automated process. Implementing these rules as proposed would require manually calculating results for these product types, leading to the potential for human errors in manual reporting. Increased margins of error would require additional METRC and OLCC (Oregon Liquor and Cannabis Commission) support to correct, which would result in additional labor burdens placed on METRC and the OLCC.

We request the analysis requirements for replicate samples match analysis and reporting requirements for primary and duplicate samples. This would only impact batches greater than 12kg. This would accomplish the goal of ensuring consistency of test results in large production batches. This would also make the reporting of results consistent between replicates of the same sample material and allow automated reporting, which would reduce manual errors.

The lack of a specified implementation date adds to the uncertainty around testing requirements for all licensees and makes it impossible for a business to plan and budget. We request the OHA require an October 1, 2022, effective date for the new sampling requirements. This will allow sufficient time to make all the necessary changes and manage the additional cost burden for laboratories.

OAR 333-007-0350(1)(b). Batch Requirements for Compliance Testing. "On or after July 1, 2022, a producer or grower must separate each harvest lot of marijuana or usable marijuana into no larger than 50-pound batches." [Batch size increase from 15lbs to 50lbs]

The proposed effective date of July 1, 2022, for expanding batch sizes from 15 to 50 pounds effectively creates a 66% reduction in testing revenue and will impose a substantial cost burden on laboratories. This will further encourage licensed producers to shop laboratories for high potency results. Without standardized methods in testing requirements, laboratories that adhere to more stringent quality control standards may continue to be impacted negatively.

To comply with OHA mandated control study testing rules in Oregon in 2016, Green Leaf Lab purchased additional instrumentation to ensure sufficient capacity. That instrumentation cost hundreds of thousands of dollars and will no longer be required under these new rules. The monetary responsibility associated with these instruments will still exist. The cost burden on laboratories compounded with the revenue loss associated with a decrease in test samples due to increased batch size limits will negatively impact small diversity laboratories.

We request the OHA change the effective date for the increase of batch sizes from July 1, 2022, to October 1, 2022. This is before the fall harvest and will allow sufficient time to address resources required to offset the decrease in revenue.

OAR 333-007-0425. Standards for Mycotoxin Contaminants Compliance Testing [Addition of new testing requirements]

The proposed effective date of July 1, 2022, for Mycotoxin compliance testing will be difficult to execute for small minority and women owned laboratories due to lack of access to capital compounded by operational difficulties due to the global pandemic.

The OHA claims mycotoxins and pesticides can be tested on the same instrument, however, for small laboratories to comply with industry demands on turn-around time additional instrumentation is required. We have priced the cost to perform Mycotoxins testing as follows: LCMSMS ($300k), method development time and consumables ($25k). This estimate of $325k does not include increased costs due to the current inflation rates, nor consider the time involved in ordering supplies, waiting for delivery, and installation. Due to the pandemic, orders that previously took 6 weeks are now taking 4 months. Service calls for engineers to set up instrumentation previously available within a month are now months out. ORELAP (Oregon Environmental Laboratory Approval Program) is already behind their current accreditation schedule due to the global pandemic without having the additional burden of these new accreditations. If ORELAP is unable to take the time to accredit properly, then the OHA is setting up the testing industry to have even more lack of standardization than before.

We request the OHA change the effective date for Mycotoxin testing from July 1, 2022, to October 1, 2022, to allow sufficient time to execute the required changes, considering all the difficulties running a business during a global pandemic and to give diversity businesses an opportunity to participate. This will also allow ORELAP time to get back on schedule.

OAR 333-007-0390. Standards for Microbiological Contaminants Compliance Testing [Addition of new testing requirements]

The proposed effective date of January 1, 2023, for Microbiological Contaminant testing will be difficult to execute for small minority and women owned laboratories due to lack of access to capital and compounded business difficulties due to the global pandemic.

We have priced the cost to perform Microbiological testing as follows: Instrumentation $50k, small lab equipment $100k, method development time and consumables $15k, 2FTE $100k. This total of $265k does not include increased costs due to the current inflation rates, nor consider the time involved in ordering supplies, waiting for delivery, and installation. Due to the pandemic, orders that previously took 6 weeks are now taking 4 months. Service calls for engineers to set up instrumentation previously available within a month are now months out. ORELAP is already behind their current accreditation schedule due to the global pandemic without having the additional burden of these new accreditations. If ORELAP is unable to take the time to accredit properly, then the OHA is setting up the testing industry to have even more lack of standardization than before.

The OHA asserts that laboratories may be able to recoup revenue lost from the elimination of control studies and increased flower batch size from 15lbs to 50lbs (approx. 66% reduction in revenue) by adding Microbiological testing. The OHA fails to address the capital and time needed to build out a Microbiological testing department, staff training and ORELAP accreditation process and timeline.

We request the OHA change the effective date for Microbiological testing from January 1, 2023, to July 1, 2023, to allow sufficient time to execute changes required considering all the difficulties running a business during a global pandemic and to give diversity businesses an opportunity to participate. This will also allow ORELAP time to get back on schedule.

OAR 333-007-0415. Standards for Heavy Metal Compliance Testing [Addition of new testing requirements]

The proposed effective date of January 1, 2023, for Heavy Metal compliance testing will be difficult to execute for small minority and women owned laboratories due to lack of access to capital and compounded business difficulties due to the global pandemic.

We have priced the cost to perform Metals testing as follows: Microwave $100k, ICPMS (Inductively Coupled Plasma Mass Spectrometry) instrument $250k, hood and small equipment $15k, method development time and consumables $10k, 2FTE $100k. This total of $475k does not include increased costs due to the current inflation rates, nor consider the time involved in ordering supplies, waiting for delivery, and installation. Due to the pandemic, orders that previously took 6 weeks are now taking 4 months. Service calls for engineers to set up instrumentation previously available within a month are now months out. ORELAP is already behind their current accreditation schedule due to the global pandemic without having the additional burden of these new accreditations. If ORELAP is unable to take the time to accredit properly, then the OHA is setting up the testing industry to have even more lack of standardization than before.

The OHA asserts that laboratories may be able to recoup revenue lost from the elimination of control studies and increased flower batch size from 15lbs to 50lbs (approx. 66% reduction in revenue) by adding Heavy Metals testing. The OHA fails to address the capital and time needed to build out a Heavy Metals testing department, staff training and ORELAP accreditation process and timeline.

We request the OHA change the effective date for Metals testing from January 1, 2023, to July 1, 2023, to allow sufficient time to execute the required changes considering all the difficulties running a business during a global pandemic and to give diversity laboratories time to participate. This will also allow ORELAP time to get back on schedule.

CONCLUSION

Requiring expanded quality control testing for Oregon's industry is important to protect consumers and public health and safety. The thoughtful implementation of these rules will either support a diverse and safe industry or will create more regulatory burdens that could easily harm diversity and undermine competition. The timelines associated with the proposed rules are likely to have the unintended impact of labs closing due to their inability to garner capital in such a short time period and eliminate diversity participation in the testing market.

Ensuring healthy competition in the laboratory environment means lower testing costs for producers and processers. If there is not enough competition, testing prices for producers and processors could easily become substantially higher than those estimated.

These important rules should also consider the ability of laboratories to perform and execute them. The OHA is recommending rules that will substantially decrease laboratory revenue (elimination of control studies and the increase of flower batch sizes) while requiring laboratories to outlay significant capital (mycotoxin, metals, and microbiological testing) within months after decreasing laboratory revenue. The OHA's analysis of balancing producers/processors costs compared to laboratories revenue loss and capital requirements fails to consider the impacts on small diversity laboratories. The implementation dates will have a significant cost impact that has not been addressed.

Reducing laboratory revenue within a short time frame of requiring substantial capital expenditure could significantly pose an issue to laboratories and the viability of Oregon's testing industry. Without enough time for laboratories to be able to comply with these rule changes there may result in fewer laboratories and less throughput resulting in higher testing prices due to lack of competition.

The lack of clarity for implementation dates in some of the proposed rules is confusing and sets up laboratories for failure. Proposed rules with effective dates that do not consider the issues around operating a business during a global pandemic such as shipping delays, vendor delays, hiring difficulties for both laboratories and vendors that supply services and goods to laboratories, as well as supply shortages put unwarranted strain on small minority and women owned laboratories. Many small businesses have experienced operational difficulties with the pandemic in the last couple of years, cannabis and hemp testing laboratories included. These timelines also fail to address the ability of ORELAP to timely implement the additional accreditations when this agency has also been impacted by the global pandemic.

Green Leaf Lab has invested hundreds of thousands of dollars to comply with OHA mandated rules over the years. These proposed rules will negatively impact capital investments made in the past that have relied on these rules, while reducing revenue. These rules will also require a substantial amount of capital investment around the same time that revenue will be decreased. Oregon's cannabis industry has experienced a decrease in women and minority owned businesses since Oregon's recreational legalization in 2016. Oregon has taken this issue seriously recently and has addressed multiple steps to rectify this past oversight. We ask that the OHA consider our requests to extend the effective dates to allow sufficient time for small minority women owned laboratories to implement and execute on the final proposed rules. This will not only support a diverse industry but will ensure more competition in the laboratory testing marketplace so that prices are not increased due to a lack of testing laboratories that can offer these new services.

Please contact me with any further questions.

Rowshan Reordan

Rowshan.reordan@greenleaflabs.com
503-250-2912
CEO & Founder
Green Leaf Lab
12025 NE Marx St, Portland, OR 97220

EXHIBIT 15

From: Sam Tracy
To: Public Health Rules
Subject: Comment regarding drafting error in proposed changes to Chapter 333
Date: Monday, February 21, 2022 7:37:49 AM

Hello,

While reviewing the proposed changes to Chapter 333 I noticed a drafting error that, while minor, is repeated many times and could cause issues for people trying to understand and comply with the regulations.

The error is that the word "contaminate" (or "contaminates") is sometimes used when "contaminant" (or "contaminants") is the proper word. "Contaminate" is a verb, while "contaminant" is a noun.

While these sound similar in speech, I worry that this error could cause problems for people reviewing the regulations — for example, if someone was trying to identify all of the provisions regarding contaminants by searching for "contaminant" they could miss relevant items because the word "contaminate" was accidentally used instead.

Searching the document, "contaminate" appears 15 times. I reviewed all of these, and in each instance, "contaminant" is the proper word. Most of these errors appear in the rule summaries, but 6 of them are in the text of the proposed rules (always as part of the term "microbiological contaminates"). This could be quickly fixed by removing each use of "contaminates" and using "contaminants" instead.

Thank you for all of your work on these regulations, and please let me know if you have any questions.

Best,
Sam
--
Sam Tracy | Associate
VS Strategies
sam@VSStrategies.com
www.VSStrategies.com

EXHIBIT 16

From: Sherman Hom
To: Public Health Rules
Subject: Public Comment concerning Marijuana and hemp testing and laboratory accreditation standards
Date: Friday, January 14, 2022 7:20:08 AM

To whom it may concern:
I would like to recommend a change in Section:
333-007-0390 Standards for Microbiological Contaminants Compliance Testing
(3) Aspergillus speciation testing shall be performed using a qPCR analysis or alternate DNA-based method on sample material that has been enriched in fungus-specific media for a minimum of **48** hours.

to read

Aspergillus speciation testing shall be performed using a qPCR analysis or alternate DNA-based method on sample material that has been enriched in a media that supports the growth of fungi for a minimum of **24** hours.

AOAC certified qPCR methods have been validated using different cannabis sample types, such as flower, infused products, oils & concentrates, as well as industrial hemp, where a 24 hour enrichment was part of the sample processing before analysis with the qPCR assay.

I thank you for accepting this public comment for the record.

Respectfully,
Dr. Sherman Hom

--
Sherman Hom, PhD
Director of Regulatory Affairs
Sherman.hom@medicinalgenomics.com
862-588-9898
www.medicinalgenomics.com

HIGH SCIENCE® is coming to CannMed 2022! Be a part of changing the narrative on cannabis science. - **BUY TODAY!**

EXHIBIT 17

From: Tyler Wolk
To: Public Health Rules
Subject: No! on cannabis labs rule change
Date: Monday, February 21, 2022 1:05:46 AM

My name is Tyler Wolk and I'm one of the owners of juniper analytics. I Have a lot to share but to put it all into an email is difficult. My biggest problem is the 50 lb batch size and inflated testing in potency. I wanna address this from two viewpoints as an owner and as a customer/patient. From my view as a lab owner I don't wanna see my testing market shrink when it's already so hard to find business with all the labs that are cheating data! I have been operating at a loss for the last three months because of the lack of tests in the market and now you wanna change the batch size to 50lb. Do you have any idea how many less samples there will be in the market? I can tell you a lot and there already are not enough tests for the 20 labs that's why there are so many labs cheating numbers to gain business at the moment. Maybe you should work on that before changing any new rules. My other issue is when you all set the standard originally the batch size was smaller and you have already raised it how many times are we as lab owners just supposed to take these losses. You do understand that we buy equipment based on how many tests we expect and when you change the rules and require less samples we can not make money. It seems you all are only ever worried about growers making money . When I spoke to multiple people they told me you all planned to increase the batch to 50lbs because when we add metals the test would be too expensive. That's bs right now i charge $225 for a full compliance test on a 15lbs batch that's $15 per pound even if we added metals and the test went to $700 that's still only $46 per pound. You're telling me that they can't afford that difference in price you're being lied to. The other issue i just wanna voice now is about metals i personally don't believe that we should add them because i don't believe enough people will fail the growers will complain that they never fail and it's too expensive then you all will be reduce the amount of times they will be doing it and i will be stuck footing the bill just like this 50lb batch thing. THere needs to be more concrete rules that we can count on for years, not something you change your mind on every couple of years. But I can tell you without some serious changes to the market I will be out of business in a couple months and I'm the only lab within 100 miles in any direction so that should tell you something about how bad the market is.

Now for my view as a customer/patient. I Can't for the life of me understand why you would think it's better to go to a 50 lb batch to make sure a product is safe for consumption when it's smoked a gram at a time. Clearly you're only worried about the growers and not the customer.

I hope I didn't come off rude. I'm not trying to be, I'm just very frustrated with everything going on in this market right now and I'm looking to you all for regulation on the things that are hurting our business like inflated potency. Also I think if all new Lab rule changes could be held by a vote by all 20 labs there is no reason why we don't have more say in this rulemaking and I don't just want meetings but an actual poll sent to us to vote on.

Thank you

Tyler Wolk