Comment ID: 1
First Name: James
Last Name: Ruscitto
Commenter Email: jamesruscitto@yahoo.com
Comment Input Method: Portal
Commenter Association:
Commenter Title:
Posted Date: 11/27/24 10:51:26 AM
Comment:
Name: Ruscitto , James Submission Date: 11/27/2024 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 Prices that are much higher than can be found on the street defeats the purpose of stopping illegal sales.

Comment ID: 2
First Name: Lou
Last Name: Rinaldi
Commenter Email: ljrinaldi@alumni.albertus.edu
Comment Input Method: Portal
Commenter Association:
Commenter Title:
Posted Date:
Attachments:
PR2024-053.pdf
Comment:
Name: Rinaldi, Lou Submission Date: 11/27/2024 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 PR2024-053 Recommendations: ? Section 21a-421j-39 ? Home Grow The current restrictions on home grow effectively prevent growers from ?phenotype hunting,? or experimenting with crossbreeding of various genetics to achieve desired traits. This process functionally requires more than three mature and three immature cannabis plants at any given time. The plant size limitation also effectively prevents cloning because the plant has not sufficiently matured to produce viable shoots at that stage of its growth cycle. Regardless of the underlying motivation(s) behind these seemingly arbitrary restrictions, a more practical and realistic set of guidelines should be substituted in place of the current language. ? Section 21a-421j-14(n) ? Remediation ?disclosure? When we buy milk at a grocery store, the label discloses that the specific, individual product has undergone pasteurization. There isn?t a catch-all sign posted in the dairy section that says, ?Some of these products may have been treated.? It should be no different for the individualized disclosure of cannabis remediation. This is a public health issue and should be treated seriously as such. The FDA requires that irradiated foods bear the international symbol for irradiation; they carry the Radura symbol along with the statement ?Treated with radiation? or ?Treated by irradiation? on the food label. Bulk foods, such as fruits and vegetables, are required to be individually labeled. Any cannabis product that has undergone similar treatment should also carry the Radura on the label, no matter when in the cultivation process the treatment occurred. There is federal precedent here going back to 1986. ? Section 21a-421j-22 ? Medical Supply Shortages Regarding the commissioner?s discretionary ability to ?classify certain products as medical marijuana products? in the event of a shortage: The patient-centric approach would be the inverse; mandate a minimum level of inventory for all designated medical products across all retailers, and any excess/overflow from that inventory can be reallocated to adult-use sales on a discretionary basis, such as when the product is nearing its expiration date. This approach puts patients first, rather than adult-use consumers, which is only proper given how this entire industry was built on the backs of medical cannabis patients. PR2024-053 Notable Omissions: ? Public access to lab testing, subsidized by the incumbent licensed producers As of July 1, 2023, all adults in Connecticut can legally grow cannabis at home. Accordingly, residents should be able to utilize the state?s licensed testing laboratories to analyze their home-grown cannabis. Since four out-of-state corporations enjoy full control of the cannabis supply chain in our state, they should subsidize any related costs for public access to lab testing. As of March 2023, only a single cannabis testing lab is operating in Connecticut, and that lab has already gone on record as supporting this expanded access to their services. The director of this lab also confirmed his support of this proposal in a January 26th, 2024 email. ? Elimination of all remaining inaccurate strain names for medical products (i.e. ?Indicol TP?), and reversion to the true strain names. The time has come to finally do away with the fake pharmaceutical-sounding strain names in the medical program. The adult-use market has already made this change, and patients should not be burdened with having to use a Rosetta stone just to figure out the true genetic lineage of their medicine. Producers want this to happen, retailers want it to happen, patients want it to happen, and there?s no reason to perpetuate the farce of the inaccurate names any longer.

PR2024-053 Recommendations:

- *Section 21a-421j-39 – Home Grow*

The current restrictions on home grow effectively prevent growers from "phenotype hunting," or experimenting with crossbreeding of various genetics to achieve desired traits. This process functionally requires more than three mature and three immature cannabis plants at any given time. The plant size limitation also effectively prevents cloning because the plant has not sufficiently matured to produce viable shoots at that stage of its growth cycle. Regardless of the underlying motivation(s) behind these seemingly arbitrary restrictions, a more practical and realistic set of guidelines should be substituted in place of the current language.

- *Section 21a-421j-14(n) – Remediation "disclosure"*

When we buy milk at a grocery store, the label discloses that the specific, individual product has undergone pasteurization. There isn't a catch-all sign posted in the dairy section that says, "Some of these products *may* have been treated." It should be no different for the individualized disclosure of cannabis remediation.

This is a public health issue and should be treated seriously as such. The FDA requires that irradiated foods bear the international symbol for irradiation; they carry the **Radura symbol** along with the statement "Treated with radiation" or "Treated by irradiation" on the food label. Bulk foods, such as fruits and vegetables, are required to be individually labeled. Any cannabis product that has undergone similar treatment should also carry the Radura on the label, no matter when in the cultivation process the treatment occurred. There is federal precedent here going back to 1986.

Radura symbol for reference:

- *Section 21a-421j-22 – Medical Supply Shortages*

Regarding the commissioner's discretionary ability to *"classify certain products as medical marijuana products"* in the event of a shortage: The patient-centric approach would be the inverse; mandate a minimum level of inventory for all designated medical products across all retailers, and any excess/overflow from that inventory can be reallocated to adult-use sales on a discretionary basis, such as when the product is nearing its expiration date. This approach puts patients first, rather than adult-use consumers, which is only proper given how this entire industry was built on the backs of medical cannabis patients.

PR2024-053 Notable Omissions:

- *Public access to lab testing, subsidized by the incumbent licensed producers*

As of July 1, 2023, all adults in Connecticut can legally grow cannabis at home. Accordingly, residents should be able to utilize the state's licensed testing laboratories to analyze their home-grown cannabis. Since four out-of-state corporations enjoy full control of the cannabis supply chain in our state, they should subsidize any related costs for public access to lab testing. As of March 2023, only a single cannabis testing lab is operating in Connecticut, and that lab has already gone on record as supporting this expanded access to their services. The director of this lab also confirmed his support of this proposal in a January 26th, 2024 email.

- *Elimination of all remaining inaccurate strain names for medical products (i.e. "Indicol TP"), and reversion to the true strain names.*

The time has come to finally do away with the fake pharmaceutical-sounding strain names in the medical program. The adult-use market has already made this change, and patients should not be burdened with having to use a Rosetta stone just to figure out the true genetic lineage of their medicine. Producers want this to happen, retailers want it to happen, patients want it to happen, and there's no reason to perpetuate the farce of the inaccurate names any longer.

Comment ID: 3
First Name: Mark
Last Name: Plavecki
Commenter Email: marrknmaddieforever@gmail.com
Comment Input Method: Portal
Commenter Association:
Commenter Title: Mr
Posted Date: 11/28/24 01:06:06 PM
Comment:
Name: Plavecki , Mark Submission Date: 11/28/2024 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 I am a medical patient and have been for 5 years and I have seen a rapid decline in quality over all ! Not only quality but dirty medicine that?s often radiated creating a life less and tasteless and harmful product. In the past few weeks every single product I have purchased has been heavily irritated , there is no smell, there is no taste , there is hardly any effects ! Certainly not any that are helping medical persons like myself. I read an article that states 25 k med patients have walked away from this program and I am not surprised. You have super high prices. ;dirty products. Moldy products , un knowledgeable staff . Something has got to give ! You are reallly taking advantage of the people . Esp us medical people who are already sick and this shit is making us sicker! When does this end ! Shut down the program or make the changes because I refuse to ever spend another dime in Ct

Comment ID: 4
First Name: Kenyatta
Last Name: DeMudd
Commenter Email: KdeMudd1017@Gmail.com
Comment Input Method: Portal
Commenter Association:
Commenter Title:
Posted Date: 12/05/24 01:59:32 PM
Comment:
Name: DeMudd, Kenyatta Submission Date: 12/5/2024 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 As a cannabis worker who has been in every side of the industry for about 3 years now, working in both recreational and medical grows in Connecticut as well as Mass, I have to say some of the regulation especially for recreational markets are ridiculous and hindering the legal industry while also encouraging more people to go to illegal markets. I believe there needs to be common sense regulation reform, mainly in the promotional and marketing sectors of the industry. I do not understand why we ID people at the door confirming their of age to buy cannabis products only to not allow to them to smell or see any product to get a deeper understanding of what it is they are buying. This makes my job as a budtender extremely difficult for a reason I still do not understand fully. Also, the strict requirements on packaging and labeling need to be eased in order to promote competition in the industry, again, they dont have to cater to children but they also shouldn't be so generic it doesnt stand out often leading to the bigger growers and producers who can afford to have MORE product to stand out due to their amount of product. The names while I understand should be mindful of copyrights and names that may be too enticing to children much like tobacco however it is absolutely confusing for patients as well as workers to have random names such as "Sativarian" or "Indicol" it also is easy to cause brand confusion as so many brands are limited with naming. I think overall if the state put its place common sense regulation reform in regards to the marketing and promotion of cannabis products it would help the growth of the industry massively.

Comment ID: 5
First Name: Andrew
Last Name: Allen
Commenter Email: drew8952@gmail.com
Comment Input Method: Portal
Commenter Association:
Commenter Title:
Posted Date: 12/06/24 10:25:56 PM
Comment:
Name: Allen, Andrew Submission Date: 12/6/2024 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 The cannabis regulations should be changed to remove THC caps entirely. They are incredibly restrictive for the both the consumer and the industry. Connecticut continues to lose business to surrounding states without such regulations and continuing to keep the THC caps in place does nothing but allow the black market to continue to thrive. It?s not illegal for an adult over 21 to possess cannabis or cannabis products that exceed the limit but there is no way to purchase them legally. This creates incentive for consumers to get products they want either in other states or on the black market. Furthermore, the advertising and packaging restrictions on cannabis establishments are incredibly restrictive and counterproductive to a thriving industry. Similar to THC caps the regulations surrounding these things will continue to cause our state to lose business and will handicap the burgeoning cannabis industry.

Comment ID: 6
First Name: Vincent
Last Name: Caizzi
Commenter Email: pezcore67@yahoo.com
Comment Input Method: Portal
Commenter Association:
Commenter Title:
Posted Date: 12/08/24 08:42:02 AM
Comment:
Name: Caizzi, Vincent Submission Date: 12/8/2024 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 New regulations should be added to Section 21a-421j-39. Home Grow to allow for outside grow under the sun. Growing a plant under the sun is the most natural means of growing anything. Allowing consumers to grow plants in the backyard of their primary residence out of view of the street should be permitted. Cannabis is a plant that should be gardened like any other plant you would grow in your garden. Only allowing the growth of cannabis indoors does not make a lot of sense because the plant cannot be immediately used in plant form. It needs to be properly dried and cured before cannabis flowers become usable. Allowing consumers to grow outside would be a great change that will make a lot of home growers happy, to be able to utilize the most natural growing means to grow their cannabis. In addition, the state should also craft regulations to allow home growers to bring their homegrown cannabis to the market in a similar fashion we can do with homebrewed craft beer. Home growers use much care growing this special plant so that the quality of the cannabis is superior to what is being offered in the dispensary.

Comment ID: 7
First Name:
Last Name:
Commenter Email:
Comment Input Method: Portal
Commenter Association:
Commenter Title:
Posted Date: 12/10/24 01:04:19 PM
Comment:
Name: , Submission Date: 12/10/2024 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 Thank you for opening this matter to public comment. I am Erin Doolittle, a Marriage & Family Therapist who provided certification services for the CT MMP from 2017-2023. I have since pivoted to focus on other issues, however, I feel compelled to share my statement here. As a front line medical program behavioral health provider and patient I have experienced the CT MMP and the CT Adult Use markets personally and for a number of years. I have made a point to visit dispensaries in neighboring states and noticed multiple differences that are keeping the CT market out of the running for true success. It is unfortunate that CT appears to be fighting progress and in so doing, the public and medical communities are being denied what should be considered rightfully theirs. Despite the continued status of Schedule I Federally, CT has joined the ranks of progressive and compassionate states who have chosen to legalize cannabis for medical and recreational uses. I have spent a copious amount of time being a part of the process through testimony, written statements, and peaceful protest. As a behavioral health provider who works with those in recovery from opioid dependency it makes little sense to me why patients continue to be told their first and best choice for pain management is a highly addictive and often ineffective narcotic with a high degree of risk of addiction and fatal overdose instead of cannabis which is non-addictive and holds zero risk for fatality. The lack of advertising allowed for our public dispensaries has directly fed into continued stigmatization and fear surrounding cannabis despite exhaustive testimonies and studies provided to the CT Legislature by experts in the fields of medical and recreational cannabis, including those coming directly from UConn which has had cannabis education available as a field of study since 2014. If people don't know these dispensaries exist they will never use them. The dispensaries themselves are often described as "cold," "over sanitized," lacking in diversity, and overall, unpleasant. The bud tenders are uneducated. The product is not available for people to look at or smell. There is no shopping experience or opportunity for engagement when the only way to procure this legal substance is by making an order online, picking it up, and having no recourse if the consumer isn't satisfied. THC caps create problems for seriously ill or dying individuals as well as for individuals who may simply need a high level of THC to obtain their desired effect. No one should be shamed for what dosage they require. In many cases this is related to other medications dulling the effects of cannabis, exceedingly high levels of chronic pain, and longterm use of cannabis leading to heightened tolerance. For the record, longterm use and heightened tolerance is not the fault or failure of the individual user, it is completely common and expected. When people utilize SSRI's/ traditional antidepressants, benzodiazepines, or opioids, it is expected they will need to increase their dose at regular intervals. Nothing works the same forever, all substances have the potential to require dosage adjustments. Cannabis users should not be penalized for reacting to their medication the same way those utilizing mainstream medications do. THC caps simply make life harder and more expensive for those in need. The confusing and ongoing argument around potency has led to a market that cannot compete with other states or the legacy market. A market that does not help those in greatest need of palliative care is not a true market. Over regulation around advertising, packaging and potencies has turned off many a medical patient or recreational consumer. This hurts the state at large as millions of dollars drive out of CT and into neighboring states. If CT wants to have a thriving and healthy cannabis landscape it is necessary they cease the use of fake strain names. Our cannabis menus should look the same as every other state. It is deliberately shunning a culture that has survived mass prohibition. It is misleading consumers into believing what they find in CT only exists in CT. It makes efforts to research and examine strains unduly complicated and frustrating again, leading to dollars driving out of CT. I am in favor of home grow, small craft brands, and micro licenses for ordinary individuals who are willing and able to grow for others who cannot do so. I oppose all four of the original growers - AGL, Curaleaf, CT Pharma, and Theraplant,being allowed a continued monopoly while simultaneously supplying low quality cannabis. Each of these growers have been found to be non-compliant with standards and fined on multiple occasions. They have fought home grow rights and improvements to quality control. They have spent millions fighting small business owners and consumers in a deliberate attempt to maintain a monopoly they do not respect or deserve. The CBD and Hemp Markets have been gutted by uneducated non-consumers setting potency, advertising, and packaging limits that make it impossible for them to survive as a business. Patients and those seeking non-psychoactive CBD

products are yet again forced to go out of state or online to get their medical and behavioral health needs met. It is my hope these issues will be addressed. I have great respect and admiration for Erin Gorman Kirk, Esquire in her role as the first ever cannabis ombudsman. She is a tremendous resource and we are fortunate to have her. A patient advocate has long been needed. Working in tandem with her is the first and best step our state can make to the longterm health and viability of the CT Cannabis Medical and Adult Recreational Markets. Respectfully Submitted, Erin S. Doolittle, MA MFT

Comment ID: 8
First Name: Gretchen
Last Name: Swanson
Commenter Email: andromedagalaxy888@gmail.com
Comment Input Method: Portal
Commenter Association: cannabis medical consumer
Commenter Title:
Posted Date: 12/22/24 07:57:42 PM
Attachments:
pdfDearFederalLawmakers.pdf
Comment:
Name: Swanson, Gretchen Submission Date: 12/22/2024 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 pasted here please find copy of letter send to our cannabis ombudsman and senators thank you . i plan to send you another more specific one if i can keep myself in my place of residence . December 12, 2024 Dear Federal Lawmakers: Thank you for all the progress we have made in restoring social justice for all humans who medically benefit from consuming the marijuana plant and all humans who recreationally enjoy it. Please finish legalizing for public access, legal retail sales and general consumption by all people over age 18, all forms of the cannabis marijuana plant and all products derived from it for patient-directed medical purposes and recreational use. Pharmaceutical grade, high THC medical indica flowers consumed in a consistent regular regimen, enable me to live an active, independent life by providing palliative relief from myriad chronic complaints. When I eat these plants in decarboxylated form infused into homemade edibles, and inhale the burning vapors of the plant, I experience life changing relief from severe pain caused by scoliosis, slipped discs, nerve damage, tendon repairs, carpal tunnel, digestive irregularities, persistent migraines, multiple symptoms of menopause and previously menstrual and premenstrual stress, and the physical results and aftershocks of several car accidents (mostly not at fault or only partially fault). I also experience relief from physical manifestations of PTSD including confusion and insomnia. The cannabis indica, sativa, ruderalis, hemp and other strains of marijuana need to be accepted as safe plant medicine and made legally available through designated safe channels to all consumers. The industry needs freedom to produce a broad offering of strains, including varietals bred specifically for physical pain relief or medical effects and others for head highs or recreational effects. Raw whole cannabis flowers, flower concentrates, distilled and extracted isolates of the cannabis plant all need to be legalized. People on cannabis experience relief from medical conditions, as well as health benefits and recreational benefits. Now is the time to legalize and recognize the cannabis indica, sativa, ruderalis and hemp flowers as health supplements with medical benefits, pharmaceutical source material and recreational products. Each branch of this plant?s genetic tree has applications in different groups of people, depending the person?s genetic descent, specific individual biochemistry and reasons for consumption. Recognize, this female plant gives the best relief from the pain and suffering all women experience from menstruation, menopause and/or childbirth. All women need access to this plant for self-medication and self-directed treatment of common women?s reproductive health cycle complaints without pharmaceutical drugs and without male interference. The medical cannabis plant access program in CT has helped me lead an able, independent life by supplying medical potency 30% THC range indica flowers. Consuming the flowers alleviates severely debilitating pain from physical handicaps listed above, as well as stills and mollifies chronic spasticity in back and neck, so I can lead a normal productive active life participating in the community and economy. Side note, we have had some grave issues with consistency of supply since February 2023 recreational regulations in CT. People including myself need to have ongoing privileges to purchase and consume pharmaceutical grade high THC potency medical cannabis flowers in the whole raw flower form and make our own homemade preparations that work best for us. Since the recreational program got merged into our medical program in Connecticut, I have frequently been deprived of my correct flower medicine because the growers grind up all the pharmaceutical grade medical indica strain flowers and turn them into drug products called distilled oil vaporization units. Those pens don?t work for me, I can?t eat them, my symptoms are not fully alleviated by the pen products and the pens also cause me unwanted side effects. Also, please finish legalizing all forms of the cannabis marijuana plant and plant products for recreational consumption. Accept that the concept of ?getting high? meaning consuming a plant for the purpose of its effects on the central nervous system, in moderation or as part of a medical routine, is a healthy practice. Even for people with totally able bodies, aspects of life are sad and terrifying and challenging, and there is everything right about giving our minds ?a breather? and lifting up out of the humdrum daily routine for a little recreational loosening up, elevated perspective, inspiration and happiness. Happiness is what drives people to work and succeed. Happiness is healthy. Getting high and feeling happy is healthy in correct measures, times and places, based on one?s own discretion and depending lifestyle and profession. The marijuana plant itself is not

addictive. People who suffer constantly with cancers, diseases, pain, PTSD, gut sensitivities, etc., and find great relief with cannabis, do not want to stop taking it. The reason we do not want to stop taking what enables us to feel good and live happy healthy lives is because we want to live happy healthy able lives and feel good. It?s our human right to choose how we do this. For myself and countless others, regular consumption of the cannabis marijuana medicine plant provides safe, reliable, long term relief from or management of chronic issues, with mostly good side effects and minimal or acceptable risks. Our organic bodies do not respond well to synthesized chemicals or pharmaceutical drugs. We just want to enjoy life without debilitating pain that we would have to talk about all the time, and we want to have positive attitudes with happy smiles on our faces. We don?t want to be punished with some string of experimental surgeries. We don?t need to be rehabilitated or forced onto any products that make a drug company happy but doesn?t meet our own approval or personal choice. According to federal definitions I am technically physically disabled, due to congenital scoliosis and arthritis pain, work related carpal tunnel syndrome, lifelong insomnia, multiple allergies, leg and foot injuries and repairs, slipped discs from multiple car accidents mostly not my fault, and resistance to drug therapies. The marijuana plant is in my opinion much safer and more effective than many drug remedies, and is especially good for people who don?t want to be addicted to a drug. This plant is also much more tolerable for people who typically have adverse reactions and bad side effects to pharmaceuticals. Consistently consuming good medical potency cannabis indica marijuana plants by eating as a decarboxylated infusion into foods as well as by inhalation provides me with consistent relief from many chronic conditions that I have suffered with to varying degrees most of my life. Cannabis indica plant medicine helps relieve my asthma and allergies, helps motivate me to keep moving forward and work and provide for myself, makes it easier for me to keep a positive mental attitude and manage or alleviate stress. By consuming the cannabis plant as an herbal medical health supplement, I am able to continue participating in the pursuit of life, liberty and happiness as a free walking person. Please legalize. Cannabis flowers are not lethal, are easy to dose a little at a time and one readily knows when it?s enough by not wanting to smoke any more or not feeling like another edible. Heroin and fentanyl by comparison, are lethal in very small doses, can easily be overdosed, and people tend to take it all at once. The antidote for too much cannabis is waiting a few hours for it to wear off, eating some sugar and taking a nap. The antidote for opiates is a chemically synthesized Narcan drug you have to shoot up a person?s nose before they die. Please be sensitive to the differences between cannabis extracts and the raw plant. The raw plant has a different composition than every extracted preparation. The natural plant has naturally perfect stopping mechanisms to keep you from getting addicted, but the drug preparations squeeze away most of that natural perfectly whole plant medicine efficacy. All of it needs to be available so people can select what they like. Please make it legal for all women and all people in the United States to smoke marijuana, eat marijuana, and experience the health benefits of marijuana products without any legal allegation or social incrimination. Sincerely and thank you, Gretchen S Swanson, Milford Connecticut USA. 203-690-7684

December 12, 2024

Dear Federal Lawmakers:

Thank you for all the progress we have made in restoring social justice for all humans who medically benefit from consuming the marijuana plant and all humans who recreationally enjoy it. Please finish legalizing for public access, legal retail sales and general consumption by all people over age 18, all forms of the cannabis marijuana plant and all products derived from it for patient-directed medical purposes and recreational use.

Pharmaceutical grade, high THC medical indica flowers consumed in a consistent regular regimen, enable me to live an active, independent life by providing palliative relief from myriad chronic complaints.

When I eat these plants in decarboxylated form infused into homemade edibles, and inhale the burning vapors of the plant, I experience life changing relief from severe pain caused by scoliosis, slipped discs, nerve damage, tendon repairs, carpal tunnel, digestive irregularities, persistent migraines, multiple symptoms of menopause and previously menstrual and premenstrual stress, and the physical results and aftershocks of several car accidents (mostly not at fault or only partially fault). I also experience relief from physical manifestations of PTSD including confusion and insomnia.

The cannabis indica, sativa, ruderalis, hemp and other strains of marijuana need to be accepted as safe plant medicine and made legally available through designated safe channels to all consumers. The industry needs freedom to produce a broad offering of strains, including varietals bred specifically for physical pain relief or medical effects and others for head highs or recreational effects. Raw whole cannabis flowers, flower concentrates, distilled and extracted isolates of the cannabis plant all need to be legalized. People on cannabis experience relief from medical conditions, as well as health benefits and recreational benefits.

Now is the time to legalize and recognize the cannabis indica, sativa, ruderalis and hemp flowers as health supplements with medical benefits, pharmaceutical source material and recreational products. Each branch of this plant's genetic tree has applications in different groups of people, depending the person's genetic descent, specific individual biochemistry and reasons for consumption. Recognize, this female plant gives the best relief from the pain and suffering all women experience from menstruation, menopause and/or childbirth. All women need access to this plant for self-medication and self-directed treatment of common women's reproductive health cycle complaints without pharmaceutical drugs and without male interference.

The medical cannabis plant access program in CT has helped me lead an able, independent life by supplying medical potency 30% THC range indica flowers. Consuming the flowers alleviates severely debilitating pain from physical handicaps listed above, as well as stills and mollifies chronic spasticity in back and neck, so I can lead a normal productive active life participating in the community and economy.

Side note, we have had some grave issues with consistency of supply since February 2023 recreational regulations in CT. People including myself need to have ongoing privileges to purchase and consume pharmaceutical grade high THC potency medical cannabis flowers in the whole raw flower form and make our own homemade preparations that work best for us. Since the recreational program got merged into our medical program in Connecticut, I have frequently been deprived of my correct flower medicine because the growers grind up all the pharmaceutical grade medical indica strain flowers and turn them into drug products called distilled oil vaporization units. Those pens don't work for me, I can't eat them, my symptoms are not fully alleviated by the pen products and the pens also cause me unwanted side effects.

Also, please finish legalizing all forms of the cannabis marijuana plant and plant products for recreational consumption. Accept that the concept of 'getting high' meaning consuming a plant for the purpose of its effects on the central nervous system, in moderation or as part of a medical routine, is a healthy practice. Even for people with totally able bodies, aspects of life are sad and terrifying and challenging, and there is

everything right about giving our minds ‘a breather’ and lifting up out of the humdrum daily routine for a little recreational loosening up, elevated perspective, inspiration and happiness. Happiness is what drives people to work and succeed. Happiness is healthy. Getting high and feeling happy is healthy in correct measures, times and places, based on one’s own discretion and depending lifestyle and profession.

The marijuana plant itself is not addictive. People who suffer constantly with cancers, diseases, pain, PTSD, gut sensitivities, etc., and find great relief with cannabis, do not want to stop taking it. The reason we do not want to stop taking what enables us to feel good and live happy healthy lives is because we want to live happy healthy able lives and feel good. It’s our human right to choose how we do this.

For myself and countless others, regular consumption of the cannabis marijuana medicine plant provides safe, reliable, long term relief from or management of chronic issues, with mostly good side effects and minimal or acceptable risks. Our organic bodies do not respond well to synthesized chemicals or pharmaceutical drugs. We just want to enjoy life without debilitating pain that we would have to talk about all the time, and we want to have positive attitudes with happy smiles on our faces. We don’t want to be punished with some string of experimental surgeries. We don’t need to be rehabilitated or forced onto any products that make a drug company happy but doesn’t meet our own approval or personal choice.

According to federal definitions I am technically physically disabled, due to congenital scoliosis and arthritis pain, work related carpal tunnel syndrome, lifelong insomnia, multiple allergies, leg and foot injuries and repairs, slipped discs from multiple car accidents mostly not my fault, and resistance to drug therapies.

The marijuana plant is in my opinion much safer and more effective than many drug remedies, and is especially good for people who don’t want to be addicted to a drug. This plant is also much more tolerable for people who typically have adverse reactions and bad side effects to pharmaceuticals.

Consistently consuming good medical potency cannabis indica marijuana plants by eating as a decarboxylated infusion into foods as well as by inhalation provides me with consistent relief from many chronic conditions that I have suffered with to varying degrees most of my life. Cannabis indica plant medicine helps relieve my asthma and allergies, helps motivate me to keep moving forward and work and provide for myself, makes it easier for me to keep a positive mental attitude and manage or alleviate stress.

By consuming the cannabis plant as an herbal medical health supplement, I am able to continue participating in the pursuit of life, liberty and happiness as a free walking person. Please legalize.

Cannabis flowers are not lethal, are easy to dose a little at a time and one readily knows when it’s enough by not wanting to smoke any more or not feeling like another edible. Heroin and fentanyl by comparison, are lethal in very small doses, can easily be overdosed, and people tend to take it all at once. The antidote for too much cannabis is waiting a few hours for it to wear off, eating some sugar and taking a nap. The antidote for opiates is a chemically synthesized Narcan drug you have to shoot up a person’s nose before they die.

Please be sensitive to the differences between cannabis extracts and the raw plant. The raw plant has a different composition than every extracted preparation. The natural plant has naturally perfect stopping mechanisms to keep you from getting addicted, but the drug preparations squeeze away most of that natural perfectly whole plant medicine efficacy. All of it needs to be available so people can select what they like.

Please make it legal for all women and all people in the United States to smoke marijuana, eat marijuana, and experience the health benefits of marijuana products without any legal allegation or social incrimination.

Sincerely and thank you,

Gretchen S Swanson, Milford Connecticut USA. 203-690-7684

Comment ID: 9
First Name: Yasha
Last Name: Kahn
Commenter Email: yashakahn@gmail.com
Comment Input Method: Portal
Commenter Association:
Commenter Title:
Posted Date: 12/27/24 01:33:28 PM
Comment:
Name: Kahn, Yasha Submission Date: 12/27/2024 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 The department should collect all cannabis testing data as it would allow for monitoring of the industry, enforcement when needed, and adjustment to policy when and if the data shows the need for adjustment. The current language within Sec. 21a-408-60. Laboratory testing: (g) The laboratory shall file with the department an electronic copy of each laboratory test result for any batch that does not pass the microbiological, mycotoxin, heavy metal or pesticide chemical residue test, at the same time that it transmits those results to the producer. In addition, the laboratory shall maintain the laboratory test results and make them available in accordance with section 21a-408-72 of the Regulations of Connecticut State Agencies. The language should be changed to: (g) The laboratory shall file with the department an electronic copy of the Certificate of Analysis (COA) for each batch tested. This COA must be submitted at the same time that the results are transmitted to the producer. In addition, the laboratory shall maintain all results and COAs and make them available in accordance with section 21a-408-72 of the Regulations of Connecticut State Agencies.

Comment ID: 10
First Name: Ivelisse
Last Name: Correa Brown
Commenter Email: ivelisse1312860@gmail.com
Comment Input Method: Portal
Commenter Association: BLM860
Commenter Title: Vice President
Posted Date: 01/06/25 07:14:44 PM
Comment:
Name: Correa Brown, Ivelisse Submission Date: 1/6/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 CT DCP allows the highest mold and mildew limits for it's medical cannabis program in the country, please reduce the amount to zero and stop attempting to ban cannabis vapes. There are no 100% black or brown owned dispensaries due to overt racism in the legislation and a puppet social equity council that has provided no technical or financial assistance to people in the inner city that dream of opening their own dispensary without a white co-owner. Licenses must be easier to obtain via DCP and the state of CT at a cost DIA communities can afford. Dispensaries don't even know what they're selling and have a hard time describing amounts and products when you enter a dispensary because of laws with displays. The online system for connecticut cannabis is inefficient and confusing. It is easier to just travel to mass or RI and I'm able to purchase higher quantities with higher THC thresholds and lower mold limits. I should be able to see what I'm going to purchase, know the REAL name of the strain and see the actual quantity of the edibles or flower being purchased. The entire system is flawed and the laws are written by lobbyists. It is shameful and dangerous as written. Talk to actual cannabis consumers and not lobbyists.

Comment ID: 11
First Name: David
Last Name: Nathan
Commenter Email: dnathan@d4dpr.org
Comment Input Method: Portal
Commenter Association: Doctors for Drug Policy Reform
Commenter Title: Co-founder & Past President
Posted Date: 01/08/25 05:15:45 PM
Attachments:
National sign-on letter for IICPS 2023-08-07.pdf
IICPS infographic 2024-03-17.pdf
Comment:
Name: Nathan, David Submission Date: 1/8/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 On behalf of Doctors for Drug Policy Reform (D4DPR), I wish to express our strong support for the Connecticut Department of Consumer Protection?s adoption of the International Intoxicating Cannabinoid Product Symbol (IICPS) as an alternative to the cannabis product symbol currently in use for cannabis products in Connecticut. The IICPS is a standardized, universal cannabis product symbol that was vetted and approved as consensus standard ASTM D8441 by ASTM International through a unanimous vote of over 200 worldwide professionals and experts from the public and private sectors. The National Technology Transfer and Advancement Act (NTTAA) mandates use of consensus standards in federal regulations, so the IICPS is poised to become the national cannabis product symbol when cannabis is legalized at the federal level of the United States. Since its introduction in 2022, the IICPS has already been incorporated into the universal symbol of five U.S. states: Vermont, Montana, South Dakota, New Jersey, and Arkansas. Several other states, including Delaware, Virginia, and Minnesota, are planning its adoption in 2025. I have attached an infographic for the IICPS, along with a letter signed by 22 key organizations supporting the adoption of the IICPS by all authorities having jurisdiction in the United States. As you can see, the IICPS is vigorously endorsed by all categories of cannabis stakeholders ? industry trade groups, physicians, patients, consumers, and advocacy organizations. We appeal to the DCP to modify its regulations and adopt ASTM D8441 as an alternative to the cannabis product symbol currently in use in Connecticut. Thank you for your consideration of this important symbol of smart regulation. Respectfully Submitted, David L. Nathan, MD, DFAPA Co-founder & Past President Member, Board of Directors DOCTORS FOR DRUG POLICY REFORM (609) 688-0400 (office) | D4DPR.org | dnathan@d4dpr.org 712 H Street NE, Suite 1290, Washington, DC 20002 Attachments: 1. Infographic for the IICPS (ASTM D8441) 2. Letter from stakeholder organizations in support of IICPS (ASTM D8441)

August 2023

Doctors for Cannabis Regulation

STAKEHOLDER ORGANIZATIONS SUPPORT UNIVERSAL ADOPTION OF THE INTERNATIONAL INTOXICATING CANNABINOID PRODUCT SYMBOL (IICPS)

To cannabis regulators in the United States and around the world:

We, the undersigned organizations representing public health, social justice, patient, consumer, and industry advocacy groups, wish to declare our strong support for the adoption of the International Intoxicating Cannabinoid Product Symbol (IICPS) by all authorities having jurisdiction (AHJs) in the United States and abroad. The IICPS is defined by the international consensus standard ASTM D8441.[1,2]

Figure 1: *The IICPS for light and dark backgrounds, printed on a Montana package, and embossed on a Vermont edible*

The importance of a standardized, universal cannabis product symbol

To prevent accidental ingestion by adults and (especially) children, cannabis product packages should bear a symbol that enables people of all ages and backgrounds to identify intoxicating cannabinoids with a quick glance at a product package. To facilitate recognition and promote future interstate commerce, a well-designed cannabis product symbol should be harmonized across regional, state, and national borders, transcending language and culture.

A truly universal cannabis product symbol is a simple and highly visible indicator of whether cannabis regulators are employing best practices to protect public health and safety.

Consensus standards for safety signs

The IICPS is based upon existing consensus standards, which are technical specifications issued by standards development organizations like NIST, UL, ASTM, and ISO. They are developed in an open environment to ensure public safety and promote best practices through collaboration by professionals from both the public and private sectors.

Recognizing the importance of well-designed industry standards, the National Technology Transfer and Advancement Act of 1995 (NTTAA) requires the U.S. federal government to adopt available consensus

[1] ASTM D8441/D8441M, Standard Specification for International Symbol for Identifying Consumer Products Containing Intoxicating Cannabinoids. ASTM International: Approved February 25, 2022. https://www.astm.org/d8441_d8441m-22.html
[2] Wikipedia. “ASTM D8441/D8441M,” Accessed April 27, 2023. https://en.wikipedia.org/wiki/ASTM_D8441/D8441M

standards in federal regulations. If a federal entity seeks an exemption from the NTTAA, the head of that agency or department must provide a written explanation for non-compliance to the Office of Management and Budget (OMB). This legislation put into law what had long been considered best practice.

The bedrock consensus standard for safety signs, originally published in 1984, is ISO 3864,[3] which requires that a standard warning sign include a black graphical element within a black-bordered yellow triangle (see **Figure 2** for examples).[4] ISO 3864 corresponds to the harmonized U.S. consensus standard ANSI Z535, which defines "warning sign yellow" as Pantone 109c (Hex: #ffd100; RGB: 255,209,0; CMYK: 0,18,100,0).[5]

ISO 3864-3 specifies that the graphical element inside a warning symbol should:

- Utilize objects, concepts, and activities, or a combination of these, which are familiar to the target group
- Contain only those details that contribute to an understanding of the symbol
- Exclude any alphanumeric characters or punctuation
- Be readily associated with its intended meaning
- Be easily distinguishable from other graphical elements[6]

For cannabis products, the only graphical element that satisfies these criteria is a cannabis leaf. It is far and away the most familiar graphical element associated with cannabis. Alphanumeric characters (e.g, "THC" or "21+") and punctuation marks (e.g., an exclamation point) are prohibited in ISO 3864 compliant symbols, the sole exception being the basic warning sign with an exclamation point, which is defined in a separate standard.[7] The reason for this exclusion is rooted in principles of social justice: **Safety symbols that include text within the symbol discriminate against already marginalized communities on the basis of age, culture, language, literacy, knowledge of the Latin alphabet, and education.**

Figure 2: *Examples of ISO 3864 compliant signs in use around the United States*

Further, the inclusion of "THC" within the symbol itself erroneously implies that THC is the only intoxicating cannabinoid. While currently unregulated, there are products containing other cannabinoids, such as hexahydrocannabinol (HHC),[8] which are themselves intoxicating. Such products will likely merit labeling with the cannabis product symbol in the future, even if those products do not contain THC. Thus, any symbol with the text "THC" within the symbol will need to be abandoned.

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[3] ISO 3864-1:2011, *Graphical symbols—Safety colours and safety signs—Design principles for safety signs and safety markings*. International Organization for Standardization: Second edition, 2011-04-15. https://www.iso.org/standard/51021.html

[4] ISO 3864-2:2016, *Graphical symbols—Safety colours and safety signs—Design principles for product safety labels*. International Organization for Standardization: Second edition, 2016-12-15. https://www.iso.org/standard/66836.html

[5] ANSI Z535.1-2017, *American National Standard for Safety Colors*. American National Standards Institute, Inc. (Secretariat: National Electrical Manufacturers Association): Approved October 20, 2017. https://www.nema.org/docs/default-source/standards-document-library/ansi-z535_1-2017-contents-and-scope.pdf?sfvrsn=d7266ce_2

[6] ISO 3864-3:2012(en), *Graphical symbols—Safety colours and safety signs—Design principles for graphical symbols for use in safety signs*. International Organization for Standardization: Second edition, 2012-02-01; Corrected version 2012-06-15. https://www.iso.org/obp/ui/#iso:std:iso:3864:-3:ed-2:v2:en

[7] ISO 7010:2019, *Graphical symbols—Safety colours and safety signs—Registered Safety Signs*. International Organization for Standardization: Third edition, 2019-07; Corrected version 2020-06. https://www.iso.org/obp/ui/#iso:std:iso:7010:ed-3:v2:en

[8] European Monitoring Centre for Drugs and Drug Addiction. "EMCDDA technical expert meeting on hexahydrocannabinol (HHC) and related Cannabinoids." Lisbon: December 19, 2022. https://www.emcdda.europa.eu/news/2022/emcdda-technical-expert-meeting-hexahydrocannabinol-hhc-and-related-cannabinoids_en

Despite the ubiquity of ISO 3864 safety signs, no state regulatory body utilized that international standard until Montana adopted the IICPS in late 2021. Prior to this, individual U.S. states created their own bespoke and ironically named "universal" symbols. See **Figure 3** for a comparison of cannabis product symbols.

Development of the IICPS and ASTM D8441

The International Intoxicating Cannabinoid Product Symbol (IICPS) was developed through collaboration between Doctors for Cannabis Regulation (DFCR) and ASTM International.[9]

When designing a truly universal cannabis product symbol, the creators met and exceeded the requirements of safety sign standards, satisfying a strict set of criteria:

- Communicate a simple public health message: "Caution with Cannabis"
- Use the simplest possible design to fit within the allotted space, so that everyone – especially the visually impaired – will immediately ascertain the meaning of the symbol
- Incorporate symbology that transcends age, language, culture, literacy, knowledge of the Latin alphabet, and specialized knowledge about cannabis
- Accommodate the addition of optional text below or next to the symbol to comply with existing consensus standards and meet the needs of authorities having jurisdiction
- Limit printing/packaging costs by using only two colors (inclusive of black and white)
- Avoid package inventory waste by reducing the chance that the symbol would need to be replaced as a result of future changes in science or public policy
- Facilitate recognition at reduced sizes and low resolution, which is critical for printing on small packages and printing or embossing directly onto the surface of intoxicating cannabis products
- Permit use of the symbol free of charge by all legalized jurisdictions in the United States

The IICPS was approved as a standalone consensus standard by ASTM International's Committee D37 on Cannabis.[10] It passed by a unanimous vote of over 200 members on its first ballot in early 2022. As the first cannabis labeling consensus standard in the world, it now bears the official designation of ASTM D8441.

As specified by ISO 3864 and ASTM D8441, the IICPS is designed to accommodate alphanumeric or special characters below or next to the symbol for supplemental information. This allows for use of an unchanging, universal symbol while meeting the varying needs of authorities having jurisdiction in the United States and around the world. It also obviates any perceived need for the inclusion of letters, numbers, or special characters inside the symbol itself.

Montana was the first U.S. state to adopt the IICPS in late 2021.[11] Since then, New Jersey,[12] Vermont,[13] and South Dakota[14] have incorporated the IICPS design into their state symbols. Other states, including Alaska,[15] are considering adoption of the IICPS. See **Figure 4** for examples of the IICPS in current usage.

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[9] Doctors for Cannabis Regulation. "Universal Cannabis Symbol." DFCR website. Accessed April 27, 2023. https://www.dfcr.org/universal-cannabis-symbol

[10] ASTM International. "New Standard Provides International Symbol for Intoxicating Cannabinoids." ASTM International News Release, March 15, 2022. https://newsroom.astm.org/new-standard-provides-international-symbol-intoxicating-cannabinoids

[11] Montana Department of Revenue, General Labeling Requirements, accessed April 27, 2023. https://mtrevenue.gov/cannabis/labeling-and-packaging/

[12] New Jersey Cannabis Regulatory Commission, Business Resources, accessed April 27, 2023. https://www.nj.gov/cannabis/businesses/resources/

[13] Vermont Cannabis Control Board, Rule 2: Regulation of Cannabis Establishments, November 2021. https://ccb.vermont.gov/sites/ccb/files/2021-11/Proposed%20Rule%202%20-%20Regulation%20of%20Cannabis%20Establishments.pdf

[14] Medical Cannabis in South Dakota: Standard Cannabis Product Symbol, accessed April 27, 2023. https://medcannabis.sd.gov/Establishments/Symbol.aspx

[15] Helms, Rick & Sawyer, Jane. "Summary of the Special Working Group on Drinkables." *State of Alaska, Alcohol & Marijuana Control Office.* January 13, 2022. https://www.commerce.alaska.gov/web/Portals/9/pub/MCB/Minutes/2022/01.19/Tab5.pdf?

Symbol design	Authorities having jurisdiction (AHJs) using the symbol	Shape of outline (conventional meaning)	Emphasized color (conventional meaning)	Number of colors (including white)	Graphical element (cannabis leaf)	Large graphical element for the visually impaired	Text excluded from interior of symbol	ISO & ANSI compliant
	**IICPS:** MT, NJ, SD, & VT	Triangle (warning)	Yellow (caution)	2	Yes	Yes	Yes	Yes
	AR	None	None	2	No	No	No	No
	AZ, CO, FL, & OH	Diamond (none)	Red (prohibition)	2	No	No	No	No
	CA	Triangle (warning)	None	2	Yes	No	No	No
	CT, MA, ME, & RI	Triangle (warning)	Red (prohibition)	3	Yes	Yes	Yes	No
	MD	Triangle (warning)	Red (prohibition)	2	Yes	No	No	No
	MI	Inverted triangle (none)	Green (safe condition)	2	Yes	Yes	No	No
	NM	Diamond (none)	Red (prohibition)	2	No	No	No	No
	NV	Triangle (warning)	None	2	No	No	No	No
	NY	Square (none)	Yellow, red (caution, prohibition)	4	Yes	No	No	No
	OK	Rectangle (none)	Red (prohibition)	3	Yes	No	No	No
	OR	Rectangle (none)	Red (prohibition)	3	Yes	Yes	No	No
	WA	Diamond (none)	Yellow, green (caution, safe condition)	4	Yes	Yes	No	No
	Canada	Octagon (stop)	Red (prohibition)	3	Yes	Yes	No	No

Figure 3: Comparison of cannabis product symbols in use, May 2023. *Green indicates desirable attributes (according to international consensus standards), while red indicates undesirable attributes. Multiple consensus standards dictate that the shape of a safety sign urging caution should be a warning triangle. The emphasized color of a symbol should be consistent with existing conventions, in which red denotes prohibition, yellow denotes caution, and green denotes a safe condition. The ideal number of colors in a safety symbol is two (and white is considered a color in this context), as more colors unnecessarily increase the cost of packaging. Standard safety signs contain only graphical elements within their borders, not text or punctuation. Only large design elements should be included. Finally, safety signs should be compliant with ISO and ANSI consensus standards, as described in the text.*

In early 2023, the National Transportation Safety Board (NTSB) issued a report on driving under the influence of cannabis and other drugs, in which they referenced the IICPS as an existing consensus standard.[16] To the best of our knowledge, this is the first time a cannabis product symbol has been recognized by a U.S. federal agency.

As part of its ongoing commitment to public health and safety through the effective regulation of cannabis, DFCR commits to making these designs available in multiple file formats for use by regulators in all U.S. states, U.S. territories, and the U.S. federal government at no cost, royalty-free, and without restriction, in perpetuity.

Figure 4: *IICPS on actual product packages and embossed on lozenges*

Conclusion

We endorse the IICPS to promote public health and safety by differentiating products containing intoxicating cannabis from other products. It serves disadvantaged communities by ensuring correct identification by people of any age, culture, literacy level, or education by following the international convention of using graphical elements rather than alphanumeric characters in the design. Finally, it empowers every authority having jurisdiction (AHJ) to add supplemental text in a way that meets their constituents' needs. AHJs can easily change supplemental text in the future without needing to modify the symbol itself.

We, the undersigned organizations, urge all cannabis regulatory bodies worldwide to adopt the IICPS as a mandated "universal symbol" to be printed on all intoxicating cannabis product packages. This action will demonstrate regulators' commitment to public health and safety, standardized labeling, and existing consensus standards, with the prescience and flexibility to anticipate future changes in the nascent regulated cannabis industry.

Respectfully,

[See Signatories on following pages]

[16] National Transportation Safety Board. "Alcohol, Other Drug, and Multiple Drug Use Among Drivers." *Safety Research Report SRR 22-02.* December 13, 2022. p. 66. https://www.ntsb.gov/safety/safety-studies/Documents/SRR2202.pdf

Signatories to Open Letter from Stakeholder Organizations Supporting Adoption of the IICPS

Americans for Safe Access
safeaccessnow.org

atach.org

achemed.org

ACHEM
Association for Cannabis Health Equity and Medicine

CLERGY FOR A NEW DRUG POLICY
newdrugpolicy.org

CRCC CANNABIS REGULATORS OF COLOR COALITION
crc-coalition.org

CFCR Council For Federal Cannabis Regulation
uscfcr.org

dfcr.org
Doctors for Cannabis Regulation

gacc.io
Global Alliance for Cannabis Commerce

We are the Drug Policy Alliance.
drugpolicy.org

Immigrant Defense Project
immmdefense.org

JustLeadershipUSA
jlusa.org
JLUSA

ICANNA
International Institute for Cannabinoids
www.institut-icanna.com/en/

The JUSTÜS Foundation
justus.foundation

We Change Laws MPP We Change Lives
mpp.org

MFMM MINORITIES FOR MEDICAL MARIJUANA
minorities4medicalmarijuana.org

NATIONAL CANNABIS INDUSTRY ASSOCIATION
thecannabisindustry.org

NORML®
National Organization for the Reform of Marijuana Laws
Norml.org

Parabola Center
parabolacenter.com

SOCIETY OF CANNABIS CLINICIANS
www.cannabisclinicians.org

sSdp Students for Sensible Drug Policy
ssdp.org

VETERANS CANNABIS COALITION
EQUAL ACCESS WITHOUT STIGMA
veteranscannacoalition.org

UNLOC INC.
unlocnow.org
Unified Legacy Operators Council

Signatories to Open Letter from Stakeholder Organizations Supporting Adoption of the IICPS
(Alphabetical list)

Americans for Safe Access (ASA, safeaccessnow.org)

American Trade Association for Cannabis and Hemp (ATACH, atach.org)

Association for Cannabis Health Equity and Medicine (ACHEM, achemed.org)

Cannabis Regulators of Color Coalition (CRCC, crc-coalition.org)

Clergy for a New Drug Policy (CNDP, newdrugpolicy.org)

Council for Federal Cannabis Regulation (CFCR, uscfcr.org)

Doctors for Cannabis Regulation (DFCR, dfcr.org)

Drug Policy Alliance (DPA, drugpolicy.org)

Global Alliance for Cannabis Commerce (GACC, gacc.io)

Immigrant Defense Project (IDP, immdefense.org)

International Institute for Cannabinoids (ICANNA, www.institut-icanna.com/en/)

JustLeadershipUSA (JLUSA, jlusa.org)

JUSTÜS Foundation (justus.foundation)

Marijuana Policy Project (MPP, mpp.org)

Minorities for Medical Marijuana (M4MM, minorities4medicalmarijuana.org)

National Cannabis Industry Association (NCIA, thecannabisindustry.org)

National Organization for the Reform of Marijuana Laws (NORML, norml.org)

Parabola Center for Law and Policy (parabolacenter.com)

Society of Cannabis Clinicians (SCC, www.cannabisclinicians.org)

Students for Sensible Drug Policy (SSDP, ssdp.org)

Unified Legacy Operators Council (UNLOC INC., unlocnow.org)

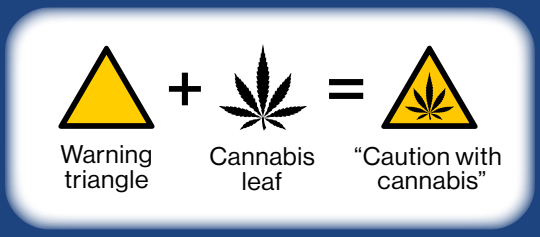
Veterans Cannabis Coalition (VCC, veteranscannacoalition.org)

PLEASE EMAIL MEDIA INQUIRIES TO: LABELING@DFCR.ORG

Doctors for Drug Policy Reform

What is the International Intoxicating Cannabinoid Product Symbol (IICPS)?

1 Combines familiar graphical elements into a symbol available free of charge

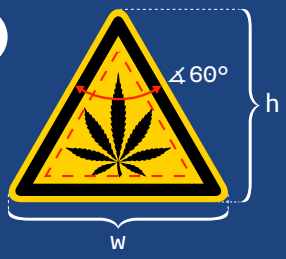


2 Colors are key

3 Simple design clear when embossed on edibles or printed at reduced sizes

4 Regulators can require text to be printed below or adjacent to the symbol

5



Approved as an international consensus standard: **ASTM D8441**

Q: Why isn't "THC" included **inside** the IICPS?

- **A.** Graphical symbols are better for children and adults who may lack specific literacy, culture, or education
- **B.** THC isn't the only intoxicating cannabinoid (e.g., HHC)
- **C.** International standards prohibit alphanumeric characters inside safety symbols
- **D.** The IICPS stays the same when text needs to be revised
- **E.** All of the above

6 Endorsed by a coalition of drug policy, clinician, patient, regulator, and industry organizations

National Cannabis Industry Association · MPP (We Change Laws. We Change Lives.) · We are the Drug Policy Alliance. · American Trade Association for Cannabis and Hemp (ATACH) · NORML · Society of Cannabis Clinicians · Minorities for Medical Marijuana · sSDP (Students for Sensible Drug Policy) · Americans for Safe Access · CRCC Cannabis Regulators of Color Coalition · Veterans Cannabis Coalition

...and many more at bit.ly/iicpsletter

7 Already in use on products and packages around the United States of America

✉ Inquiries: **labeling@d4dpr.org**

i For more information and free download: **d4dpr.org/labeling**

Comment ID: 12
First Name: Brian
Last Name: Dunphy
Commenter Email: briandunphy3@gmail.com
Comment Input Method: Portal
Commenter Association:
Commenter Title:
Posted Date: 01/09/25 05:55:26 PM
Comment:
Name: Dunphy , Brian Submission Date: 1/9/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 When CT was originally crafting cannabis laws it partnered with NY. Recently, NY's Governor signed two new laws that I hope CT will do as well. NY now has Cannabis Growers Showcase program,where producers and farmers may sell directly to patients/ customers at farmers markets/style events. In addition, the second new law classifies cannabis as an agricultural crop in the state. Switching subjects, I'm shocked and saddened to learn we allow some of the highest mold and yeast counts/ %'s in medical marijuana. How is this possible when it was approved by DCP? Shouldn't they be ensuring consumers well being as opposed to corporate profits? Lastly, it's outrageous in a democratic state that we adopt a mirror law for hemp beverages that is a carbon copy of Idaho's! It's Reefer Madness 2.0. Anyone 21 and above can walk into a package store in CT and purchase a bottle of grain alcohol- if completely consumed, the person would die of alcohol poisoning. There is no such thing with cannabis as it is not lethal and a consumer can not overdose- it's medically impossible. Don't tread backwards with the green rush. Make decisions based on medical studies, current data and common sense without bias and prejudice.

Comment ID: 13
First Name: Jason
Last Name: Blakesley
Commenter Email: jasonblakesley@live.com
Comment Input Method: Portal
Commenter Association:
Commenter Title:
Posted Date: 01/09/25 10:05:53 PM
Comment:
Name: Blakesley, Jason Submission Date: 1/9/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 Hello. My name is Jason. I am submitting comments in regards to the proposed version of regulations of adult use cannabis proposed by the Department of Consumer Protection. I am opposing the following changes to the regulations. My proposed revisions include ideas and suggestions. First of all, I oppose Sec. 21a-421j-39 Home Grow. Specifically, I am against limiting the number of plants that we can cultivate to three mature and three immature plants. It is absurd that an immature plant would be classified as under 8 inches and only 8 inches wide. In a time of shortages of medical and recreational cannabis, why are you limiting the people who want to grow their own? It would be more prudent to limit the number of plants of the large commercial cultivators, who frequently grow a product with a high mold content. Connecticut mold colony forming units (CFU) is 100,000 where Massachusetts is 10,000. Also, the current companies are not successful in meeting the demand of patients and consumers. If a commercial grow is allowed to have a minimum of 10,000 square feet, shouldn?t a home cultivator at the very least be able to have six square feet to grow their own? A six by six area is the standard area that a grow light covers. The homegrow allowed canopy space should be measured using the same units as the commercial grow space, square footage. I believe that we should have outdoor grow rights. Currently there is a company in Connecticut, connected to former CT State Senator Art Linares, who holds an equity license, that has outdoor grow rights on an 80 acre farm, 250,000 sq. ft. of canopy, and 50,000 plants.The residents of Connecticut who pay taxes should at least be able to grow a few plants outdoors. A major benefit would also be saving money on our Eversource or United Illuminating electric bill during the outdoor growing season. What was the cost of the State Police and Massachusetts National Guard flyovers and enforcement these last couple years? Is risking the lives of our brave men and women in uniform really worth enforcing a hypocritical and unjust law? Finally, speaking of 21a-421j-29, Cannabis Testing, the current law allows for each raw cannabis batch size to not exceed 40 lbs. I believe it should be a much lower amount, at 10 lbs, in order to prevent cherry picking raw flower most likely to pass testing. Any cannabis that has failed and its extract is now being used for edibles or vapes should require a warning label saying such. In addition, the warning label should include the pesticides and fungicides the state approved cannabis cultivators apply to flowering cannabis. Many of these companies are spraying cannabis flowers with approved fungicides up to the date of harvest just to pass testing which is affecting quality and safety considerably. Thank you for taking these considerations seriously and please reach out with questions or concerns. I work in the commercial cannabis industry as a cultivator!

Comment ID: 14
First Name: Josiah
Last Name: Schlee
Commenter Email: josiahschleemedia@gmail.com
Comment Input Method: Portal
Commenter Association: CT Cannawarriors / Cannabis Advocate
Commenter Title: Cannabis Advocate
Posted Date: 01/09/25 11:37:40 PM
Comment:
Name: Schlee, Josiah Submission Date: 1/9/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 DCP Regulators, I have absolutely zero confidence in the DCP to write any laws or regulations to protect CT Medical and Adult Use Cannabis Consumers. The DCP intentionally hid a major change of allowable mold and yeast from 10,000 cfu/g to 1,000,000 cfu/g and knowingly were willfully negligent in harming cannabis consumers. The DCP needs to be investigated and charged criminally for the willful negligence. Your profit protection for the cannabis corporations is repulsive and your corruption will be exposed. Josiah Schlee

Comment ID: 15
First Name: Rebecca
Last Name: Rutenberg
Commenter Email: r.rutenberg@vicentellp.com
Comment Input Method: Portal
Commenter Association: Vicente LLP
Commenter Title:
Posted Date:
Attachments:
2025.01.09_Comment on outdoorcultivation reg - For submission.pdf
Comment:
Name: Rutenberg, Rebecca Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 Please see the attached public comment.

Vicente.

Prudential Tower
800 Boylston Street, 26th Floor
Boston, MA 02199
Tel: 617.934.2121

California · Colorado · Florida · Maryland · Massachusetts
Michigan · Minnesota · New Jersey · New York · Texas

January 9, 2025

Department of Consumer Protection
State of Connecticut
50 Columbus Blvd Suite 901
Hartford, CT 06103

To Whom It May Concern:

We provide the following comment on behalf of a client who is an expanded producer. Outdoor cultivation is permitted under the Act Concerning Responsible and Equitable Regulation of Adult-Use Cannabis ("RERACA"), but the implementing adult use regulations contain internally inconsistent language regarding the location of the growth. Even though the regulations permit outdoor cultivation in noncontiguous areas (Section 21a-421j-7(b)), another broader regulation addressing multiple license types has been interpreted to confine all cultivation operations to one single establishment location (Section 21a-421j-23(b)).

Generally, when regulations contain language addressing a more specific subject conflict with language concerning a more general subject, the specific provision will typically take precedence, meaning the more detailed law will be applied over the broader one. *See* Nitro-Lift Techs., L.L.C. v. Howard, 568 U.S. 17, 21 (2012) and the regulation permitting outdoor cultivation in noncontiguous areas should prevail over the general license requirement that operations be confined to one location. The Department of Consumer Protection ("DCP") has opted, however, to prioritize the general requirement over the more specific provision. We request that the regulations be amended to resolve the internal conflict, and create an exception from the general requirement in Section 21a-421j-23(b) to allow outdoor cultivation in noncontiguous areas as follows:

> *(b) A producer, cultivator, micro-cultivator, product manufacturer, food and beverage manufacturer, product packager, delivery service, or transporter license shall permit such licensee to operate out of a single establishment location, except that:*
>
> > *(1) a cannabis establishment changing its location may store cannabis at both the former and new location for a period of time approved by the department as necessary for transition, but in no event shall the cannabis establishment sell to consumers, qualifying patients or caregivers simultaneously at more than one location;*
> >
> > *(2) a producer or cultivator may cultivate at a noncontiguous outdoor location or locations if its grow space and outdoor grow do not exceed two hundred fifty thousand square feet in the aggregate in accordance with Section 21a-421j-23(c).*

Vicente.

Prior to operating an additional establishment at a different location, a licensee shall obtain a corresponding license in accordance with section 21a-420 of the Connecticut General Statutes. Notwithstanding the foregoing, a delivery service or transporter may maintain multiple parking locations for transport vehicles, provided that no cannabis is stored at such locations unattended, after the establishment's hours of operations, or for a period longer than twenty-four hours.

The resolution of the internal conflict in the adult use regulations will provide producers or cultivators who have reached capacity at their existing locations, but have not exceeded the aggregate limit, to find outdoor locations to cultivate in compliance with local municipal bylaws or ordinances as well as DCP regulations.

To further allow outdoor cultivation in the regulations regarding palliative use of marijuana, simply eliminating the restriction of cultivation of plants for the medical market to indoor facilities in Section 21a-408-1 and Section 21a-408-20, as well as making cultivation opportunities for the medical market consistent with the broader opportunities afforded to the adult use market will eliminate significant existing obstacles to producing medical products:

Section 21a-408-1

[(61)](55) "Production facility" means a secure~~, indoor~~ facility or location where the production of marijuana occurs and that is operated by a person to whom the department has issued a producer license under the Act and sections 21a-408-20 of the Regulations of Connecticut State Agencies;

Section 21a-408-20(c)(5)

(5) The applicant's ability to produce pharmaceutical grade marijuana for palliative use in a secure~~, indoor~~ facility or location;

These proposed amendments would allow cultivators and producers to better serve all sectors of the cannabis market in Connecticut and produce cannabis products at a lower cost to patients and consumers, so as to better combat the illicit market and prevent the current flight of consumers and patients to neighboring states. It will alleviate product availability concerns, increase investment in the state and create job opportunities.

Please contact us if you have any questions regarding the proposed regulations.

Sincerely,

Rebecca Rutenberg
Senior Vice President, Eastern Markets + Business Intelligence
Vicente LLP
R.Rutenberg@VicenteLLP.com

Comment ID: 16
First Name: Eileen
Last Name: Kopec
Commenter Email: elkopec.ek@gmail.com
Comment Input Method: Portal
Commenter Association:
Commenter Title:
Posted Date: 01/10/25 12:45:54 PM
Comment:
Name: Kopec, Eileen Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 Thank you for accepting my comments about this proposed legislation. I am a long-time CT MMP patient. I have several comments about this proposed legislation. The focus is on product labeling. As I said, I'm a medical cannabis patient. I want to know if the specific flower product that I purchase at a CT dispensary has been remediated for mold. I believe that most remediation processes reduce beneficial cannabinoids & terpenes in cannabis. I will avoid purchasing products that have undergone remediation for that reason. Any remediated products should be tested for the cannabinoid & terpene content. That should be the information that patients/consumers get on packaging contents. I personally believe that CT cannabis producers are remediating nearing all flower products because they have poor growing standards. I want product labeling to accurately describe the product contents. Something else I would like included in labeling of CT cannabis products is a warning label about the harmful environmental impact of disposal of plastic packaging & single-use vape devices & cartridges. CT has no safe disposal or recycling for any of the cannabis product packaging. Even worse there is no safe disposal for single-use vape devices & the batteries in these devices. There is no disposal of or collection of the cartridges for the "re-useable" devices. The State of CT requires the age limit warning labels on cannabis produces sold in dispensaries. There are required warnings about cannabis use in general. Lets require labeling identifying the harmful environmental impact of commercial cannabis production. Put these warnings on the excessive plastic packaging. Please label disposal of single-use vape devices as the environmental hazards that they are. Thank you for accepting my comments Eileen Kopec Groton, CT

Comment ID: 17
First Name: Steven
Last Name: Inc
Commenter Email: DaOne@OneHitOneDa.com
Comment Input Method: Portal
Commenter Association:
Commenter Title: Concerned consumer
Posted Date: 01/10/25 01:13:30 PM
Comment:
Name: Inc, Steven Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 My definition of consumer protection extends to the consumer's wallet, not simply the supply stream. The state's medical cannabis program has a stipulation that must be acknowledged by the applicant to use the smallest amount of cannabis possible until they know how the medicine affects them. Standard medicinal protocol, if the licensed facilities distributing the legal medicine had a method to administer that smallest dose. THEY DO NOT, and they have rebuffed my efforts to introduce the tool engineered for this single dose delivery. I am the inventor of OneHit OneDa. One hit is one dose. The difference is in the design for more perfect combustion of ground cannabis flower. Consuming 1/20th of the average dose (a 1 gram joint), with performance combustion, delivers the medical benefit without the additional 19 doses. Put in dollar terms if true, a two joint a day consumer may reduce their consumption by 75%, a savings of ~$5000 annually. Understandable that the dispensaries are misconstruing the benefits of a dosing program because their job is to push product to retail. The Department of Consumer Protection should be in contact with me to validate the potential of consumer savings!!!! What are we facing instead??? I present the OneHit OneDa at any venue that will allow me to talk to their patrons. My effort is STRICTLY INFORMATIONAL. I would prefer my retailers and dispensaries make the sale, but I do have to eat and they are not interested. Once I have presented the OneDa verbally, I inform the consumer that if they own a OneDa, I view them a member of my family. If they visit my home, and I hope that they ask to, I would gladly show them the refrigerator, but I tell them I will not be jumping up to feed them. HELP YOURSELF, FAM! This model is the sale of an allowed item, the instruction on how to load and consume with it, and permission to take an aspirin equivalent from MY medicine cabinet, or cannabis tray. Does the proposed legislation make this "cannabis-common" event, of puff puff pass type consumption of a joint, without the joint, and without multiple doses, ILLEGAL AS GIFTING? SERIOUSLY!!!??? That is retail $0.50 of ground cannabis I am allowing a family member to take freely as if it were a glass of water. By comparison the DCP is taking a more radical approach to enforcement than they are able to enforce. Sharing a joint is cannabis consumption and that was made legal by the voters. If 20 doses shared is legal, is my invention being profiled out of the market by the DCP not validating this tool requires a single dose and will save the CONSUMERS $5,000 A YEAR! With 16,000+ of my OneHit OneDa tools in use without a SINGLE report of the tool not performing as promised, I must ask the regulators what are you afraid of learning if we meet? Would the entirety of the legislative body be agreeable to a live experience of a single dose of cannabis, or is the perception more powerful to our legislators than the opportunity to see reality. STOP THE OVER CONSUMPTION OF CANNABIS AS MORE CONSUMPTION DOES NOT EQUATE TO MORE HIGH!!! MORE CONSUMPTION EQUATES TO LESS CANNABIS, period!! What does legalization mean if I am at risk of violating CT laws if I do the most natural thing and share a puff of cannabis with friends, old and new.

Comment ID: 18
First Name: Jennifer
Last Name: Fell
Commenter Email: jennifer@ctcannabischamber.org
Comment Input Method: Portal
Commenter Association: Connecticut Cannabis Chamber of Commerce
Commenter Title: Director of Government Affairs & Business Development
Posted Date: 01/10/25 03:40:39 PM
Attachments:
CTCCC Comment Regarding Proposed Cannabis Regulations .pdf
Comment:
Name: Fell, Jennifer Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 Please see the attached file providing feedback for the proposed Adult-Use Cannabis regulations and the Medical Marijuana regulations. Best, Jennifer

CONNECTICUT CANNABIS CHAMBER OF COMMERCE

January 10th, 2025

To the Department of Consumer Protection and the Regulation Review Committee:

We are grateful for the thoughtful leadership of the Department of Consumer Protection (DCP) in crafting these regulations for an extraordinary complex industry. Thank you for the opportunity to provide feedback on behalf of the operators.

This document is submitted by the Connecticut Cannabis Chamber of Commerce on behalf of its members with the intention to provide helpful, scientifically-founded feedback for the good betterment of our industry in partnership with the tremendous work done by the DCP.

Respectfully,

Jennifer Fell
Director of Government Affairs & Business Development
Connecticut Cannabis Chamber of Commerce
jennifer@ctcannabischamber.org
860-888-2029

CONNECTICUT CANNABIS CHAMBER OF COMMERCE

Industry Feedback Regarding Proposed Regulations For Adult Use And Medical Cannabis By The Department of Consumer Protections

Who We Are:
The Connecticut Cannabis Chamber of Commerce (the "Chamber") is a membership organization established in 2022 to promote sensible policy, responsible growth, and effective development of Connecticut's cannabis industry. We represent leaders across the Connecticut Cannabis industry, including cultivation, retail, transportation, delivery, packaging, manufacturers, food & beverage licensees, and non-leaf touching services, including lab testing services. This includes Section 149 Cultivators, Lottery Licensee Winners, and Social Equity Entrepreneurs.

Goal For The Industry: Our goal for the industry is to establish a robust industry infrastructure that delivers exceptional quality, safety, and value to patients and customers while empowering licensees to launch and thrive. Connecticut's market must remain competitive with neighboring states to sustain existing businesses and foster new growth.

Current State of The Industry: The market has now reached 60+ dispensaries, hybrids, and retailers.There are 6 cultivators and 3 microcultivators in operation with several more expected to come on line in the next quarter.

This is not a consumer friendly market and we are losing a lot of business to both the illicit market and surrounding states who have lower prices, wider variety of products, and better marketing. Last year’s legislation has certainly been a help in beginning to crack down on the illicit market, but the industry is not yet competitive with operators just across our borders. Additionally, the enforcement to shut down illegal vape shop sellers has been negligible beyond the initial enforcement by DCP. We believe there must be significantly more crackdown and punishment to non-licensed sellers of illegal, untested, untaxed, and potentially unsafe cannabis.

Connecticut’s cannabis market is incredibly regulated on every level creating a very challenging landscape to develop a business in terms of both adherence to regulation, municipality requirements, and cost to operate. When AU opened its doors in January 2023 the Total Cannabis sales reached 13.1M. By October of 2024 sales had somewhat stagnated around 24.51M, which is far below the anticipated projections. This graph starts in March of 2023 and uses DCP data. By removing the first two months of sales which were outliers, it shows that combined medical and AU sales are flat. Even with 35 more stores open in the state, the state saw a 2.1 million dollar decrease in sales from December 2023 to December 2024.

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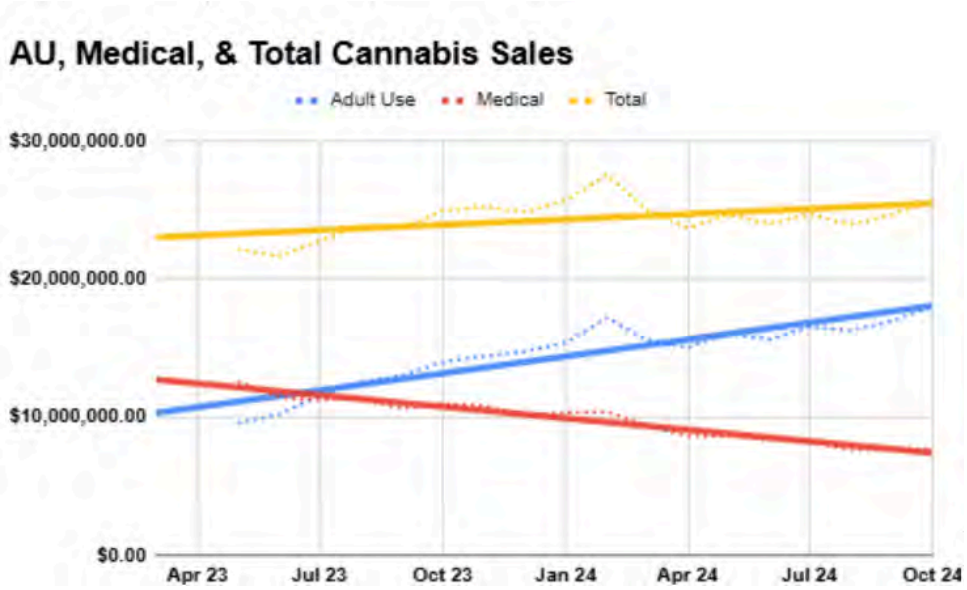

Two dispensaries have already filed to close their doors. Many more will follow if we are not mindful of the operational and financial constraints we put on the operators without true necessity. Our market has 10 years of history with Medical Cannabis. There had been great success in meeting those patients' safety and consumption needs, which have now been compromised by the regulatory demands on the industry with the role out of Adult-Use. It is the position of the Chamber that we prioritize safety with a mindful review of the industry processes and analysis of the program as the cultivators, manufacturers, and additional food and beverage licensees begin to open their doors.

Overview of Feedback:
The Department's tremendous work on the regulations will contribute positively to the industry's structure. We have some significant concerns regarding and believe the following consideration will simultaneously support the work that DCP is doing with our further hindering the industry.

Specifically regarding the proposed laboratory testing standards, the requirements to fulfill those standards, and the unidentified need for these restrictions. Based on the testimony of operating licensees and the support of its members, the chamber's position is that moving forward with the regulations as defined will be a severe detriment to an already suffering industry without demonstrated public safety outcomes. We have sighted the resources, scientific guidelines, and pertinent studies.

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PRIORITY FOR THE FEEDBACK INCLUDED IN THIS DOCUMENT

1. **Considerations for the Re-evaluation of Laboratory Testing Regulations**
    a. Inherent Heterogenity of Cannabis
    b. Final Form Testing (FFT)
    c. Stability Testing
    d. Chromium Testing
    e. Out-of-Specification (OOS) Policy
    f. Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A)
2. **Extension of P&P Timeline or Expanded Regulation Flexibilities Response to Industry Capabilities**
3. **Comprehensive Summary of Recommendations**

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1. CONSIDERATIONS FOR THE RE-EVALUATION OF LABORATORY TESTING REGULATIONS

Our concerns are based on feedback from the industry, a literature review, and a recent study completed in partnership with a producer and the labs. From our perspective, it is clear that the current testing regulations are a hindrance on accuracy, price, and efficacy.

a. INHERENT HETEROGENITY OF CANNABIS

Regulations Proposed by DCP:

Homogenized Batch Preparation

Section 21a-421j-29(e):
Prior to a cannabis testing laboratory collecting samples for certificate of analysis or stability testing, a cannabis establishment shall:

- Prepare each cannabis batch in its **homogenized, final form**.
- Conduct a visual inspection for foreign matter.
- Ensure consistency and integrity between the batch and the samples taken for testingogenous Batch Sampling**

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Section 21a-421j-29(g):
To ensure reliable testing, random samples taken from a cannabis batch must be representative of the **homogeneous batch**. Representative sampling requirements include at least four-tenths of one percent of the batch or specific weights or unit quantities for raw cannabis or cannabis products .

Hod Shelf-Stability Requirements Section 21a-421j-25(a):
Cannabis intended for sale must be **homogeneous** and shelf-stable for a minimum of 60 days after opening without refrigeration. This ensures consistency in cannabinoid and terpenoid concentration within the product.

Definitions of the regs

(8) "Batch" means (1) a specifically identified quantity of cannabis trim and cannabis flower, uniform in character and quality, from the same seed stock or cuttings taken from cannabis plants of the same genotype and phenotype, that has undergone the same propagation and cultivation processes, and harvested within a seventy-two hour period, in the same environment, and cured under the same conditions, or (2) a distinct group of cannabis product, uniform in character and quality, that has been produced in the same environment, under the same conditions, and from the same processes, equipment, and ingredients during the same cycle;

(41) "Homogenous" or "Homogenized" means uniform in cannabinoid and terpenoid concentration;

(68) "Sample" means a portion or part of a batch, the characteristics of which represent, as accurately as possible, the entire batch, allowing for the cannabis testing laboratory testing results of the sample to be generally applied to the entire batch;

Discussion:

Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A) notes a statistically significant variance in microbial and potency results in three methods of evaluation:

- Within the the same cannabis batch
- When retesting the same sample
- When the same batch cannabis is tested in different labs
- Batch homogenization before testing— is an unfeasible standard given cannabis's natural heterogeneity.

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Plant Heterogeneity: Cannabis is a complex botanical product with natural variability in composition. Heavy metals, including chromium, may accumulate differently across parts of the plant (e.g., roots, stems, and flowers), making representative sampling difficult.

Inherent Heterogeneity: Cannabis is a natural product with significant variability in cannabinoid and terpene concentrations across different parts of the plant. Even within a single batch, slight differences in moisture content, particle size, or composition can lead to inconsistent test results.

Formulation Variability: Final products like edibles, tinctures, and topicals are often complex formulations that require homogenization for accurate testing. Achieving and verifying this homogenization is difficult, especially for products like infused flower or layered edibles.

Heterogeneity Recognition of Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

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b. FINAL FORM TESTING (FFT)

Regulations Proposed by DCP:

Preparation in Final Form: Section 21a-421j-29(e): Before a cannabis testing laboratory collects samples for a certificate of analysis or stability testing:

- The cannabis batch must be prepared in its homogenized, final form.
- A visual inspection for foreign matter is required.
- The entire batch must be placed in final packaging to ensure consistency and integrity between the batch and the sampled product.

Batch Size and Testing: Section 21a-421j-29(g): Representative random samples must be taken from batches prepared in their final form. Sample quantities depend on the batch size to ensure accurate representation and testing.

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Isolation of Final Form Batches During Testing: Section 21a-421j-29(h): While a batch is being tested for a certificate of analysis, it must be withheld from use, stored securely, and only released upon satisfactory test results.

Packaging and Labeling: Section 21a-421j-30(f): Cannabis or cannabis products may only be labeled with a product name if their composition matches the registered final form and the cannabinoid/terpenoid profiles fall within 90–110% of the registered values.

Storage and Handling Requirements For All Found in The Regs: Section 21a-421j- 24. Minimum requirements for the storage and handling of cannabis by a producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter. (a) A producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter shall: (1) Maintain all production, manufacturing, handling and storage areas with adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions for cannabis that meet the standards set forth under 21 CFR Part 211 Subpart C except as otherwise expressly permitted by the commissioner, and except that outdoor grow handling and storage areas need only meet the requirements of these policies and procedures;

- Section 21a-421j-25. Cannabis Manufacturing Restrictions. (a) Except as otherwise provided in section 21a-421j-28 of these Policies and Procedures, cannabis permitted for sale to a consumer, qualifying patient or caregiver shall meet the following requirements, and any cannabis not in compliance with this section shall be deemed adulterated:
- (1) Cannabis shall be homogenous and shelf-stable for a minimum of sixty days after opening without refrigeration. (2) Cannabis products shall only be produced and manufactured in compliance with 21 CFR Part 211 Subpart B, (A) using ingredients and components permitted by the U.S. Food and Drug Administration for the specified use in food or food manufacturing pursuant to the Substances Added to Food inventory, if edible, (B) with equipment that meets the standards set forth under 21 CFR Part 211 Subpart D, and (C) in facilities that meet the standards set forth under 21 CFR Part 211 Subpart C.
- (D) Documenting the chain of custody of all cannabis, in compliance with 21 CFR Part 211 Subpart J, which documentation shall include, but not be limited to, the name of each employee that conducts an activity required to be recorded.
- Connecticut Food, Drug and Cosmetic Act, sections 21a91 to 21a-120, inclusive, and sections 21a-151 to 21a-159, inclusive, of the Connecticut General Statutes, regarding bakeries and food manufacturing establishments.
- Section 21a-421j-29. Cannabis Testing Laboratory Processes and Testing. (g) [On or before] Prior to January 1, 2025, the number of random samples, sufficient to ensure a

representative sampling, taken from a cannabis batch [must] shall be representative of the homogenous batch to ensure reliable testing. On or after January 1, 2025, the quantity and number of cannabis samples taken for certificate of analysis testing pursuant to subsection (i) of this section shall be taken at random, sufficient to ensure representative sampling of the corresponding batch. Representative samples shall consist of at least four tenths of one percent of the batch, but in no circumstance less than twenty grams for raw cannabis or, for cannabis products, the number of units required in accordance with the following table:

Discussion: In 2018, under the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), California implemented Final Form Testing but abandoned it in 2020 with Assembly Bill 1470 due to inefficiency and high costs to the detriment of the industry with no added value to consumers or regulators. Assembly Bill 1470 redefined “final form” to mean “the unpackaged product as it will be consumed,” allowing for batch testing of unpackaged products. This shift reduced waste, improved efficiency, and highlighted the failure of final form testing. Packaging can be tested as part of process validation, including the evaluation and qualification of container-closure systems and stability determinations for finished product batches.

- "...In the pharma [industry], you don't test the product in it's final packaging.... but you can be delivered that final form in bulk to test the product...get the COA...release it...then package it."
- "Every sample sent to a lab has to be opened by a lab technician. Multiply this mind-numbing time-losing activity by thousands of samples."
- **Testing in Final Form vs Final Packaging:** https://youtu.be/oNq-bL6Vimk?si=kCCl4xgrJNiY75t1

While FFT intends to that cannabis products meet safety and quality standards, its implementation presents significant challenges, particularly for high-variability products and small businesses. Addressing these issues requires regulatory flexibility, improved testing methodologies, and consideration of alternatives like IBT to balance safety, cost, and efficiency.Final Form Testing (FFT) in cannabis presents several challenges related to practicality, consistency, and cost. These issues stem from the inherent variability in cannabis products, the complexities of testing processes, and logistical constraints. Below is an overview of the primary challenges:

- **Conflicting Recovery Standards**: The state’s recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures.
- **Final Form Testing Intent** is to test the product at the point of consumption. Notably to identify if the package is creating contamination. Packaging can be tested independently for potential contaminates that could bio accumulate.

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Increased Opportunity For Error:

- **21 CFR Part 211 Subparts B, C, and D** as referenced the DCPs Proposed Regulations speak repeatedly to the mitigating the opportunity for mixups, and keeping products labeled, and making sure that facilities are structured to accommodate these demands of operation. These newly referenced regulations speak to mix-ups and concerns that they would use to prep in a pharmaceutical facility
- **FFT testing requires operators** to hold on 6-10 weeks of unlabeled product, in secure storage space, that the facilities were not designed to manages. This inherently required operators to act in direct opposition to the **21 CFR Part 211** guidelines.

Costly Process: Testing every individual product in its packaged, "final form" state can significantly increase costs for producers, as each variant and SKU requires separate testing.

Delayed Time Frame For Product To Get To Market: Final form testing requires that every unique product be tested after packaging, which complicates supply chain workflows and slows down the release of products to market.

Randomized Sampling: Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.

Disproportionate Burden on Small Operators: Smaller cannabis businesses often lack the resources to manage the increased costs and operational complexity associated with FFT.

Replicability Issues: Laboratories may produce varying results for identical products due to differences in equipment, methodology, or sample preparation. This lack of standardization complicates regulatory compliance.

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

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c. STABILITY TESTING STANDARDS

Regulations Proposed by DCP:

Stability Testing in Final Packaging

- Section 21a-421j-30(b): Stability testing is mandatory for cannabis products in their final packaging, including:
    a. The first registered batch in each product category.
    b. First batch of each registered beverage, edible product, or vape oil.
    c. Stability testing intervals: 30 and 60 days.
    d. Samples must undergo cannabinoid, heavy metal, and microbial testing.
    e. The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis.

Homogeneity in Final Packaging

- Section 21a-421j-30(e): If stability test results fall outside the acceptable range (90–110%), the label must be updated to reflect the actual composition and expiration date. This ensures that the cannabis or cannabis product in final form matches its registered attribute*s.*

Discussion:

Stability Concerns: FFT often requires that cannabinoid content remains within a specific percentage of the labeled claim over time (e.g., ±10%). Due to the natural degradation of cannabinoids and terpenes during storage, many products fail stability tests despite being safe and effective.

Time Frame: Due to FFT, products may not make it out the door before they need to be submitted for 30 and 60 day stability testing.

Potency Variability with Stability Testing and Conflicting Recovery Standards: The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis. Additionally, the state's recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures."By unnecessarily reporting results to the one-hundredth percentile, some labs created an unrealistic illusion of precision that raises false expectations regarding the degree to which accuracy is possible, given the 20% variation observed."
https://www.canorml.org/business-resources-for-cannabis-brands/how-accurate-is-cannabis-potency-testing/

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Packaging Interference: Packaging materials can interact with the product during testing, introducing variables that skew results (e.g., THC adhering to certain plastics).

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Replace stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

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d. CHROMIUM TESTING

Regulations Proposed by DCP:

Section 21a-421j-29(i)(3):

- Cannabis samples must be tested for heavy metals, including chromium, to ensure compliance with the following thresholds:
  - Inhalation Route: ≤ 0.6 µg/g
  - Non-Inhalation Route: ≤ 2.0 µg/g
- These limits ensure the product is safe for consumption or use according to the intended delivery metho*d.*

Discussion: Chromium is not commonly tested in cannabis products across most states. This concern is better addressed through periodic monitoring within a comprehensive Hazard Analysis and Critical Control Points (HACCP) program rather than testing individual products. Such an approach allows for proactive identification and mitigation of contamination risks in cultivation environments.

However, we recognize the unique risks posed by vaporizable cannabis products, where chromium may accumulate in heating elements or delivery systems. These scenarios may require alternative considerations, including targeted testing or material-specific evaluations, to ensure consumer safety.

Differentiation of Chromium Species: Chromium exists in multiple oxidation states, primarily trivalent (essential and less toxic) and hexavalent (highly toxic). Accurately differentiating

between these species requires advanced instrumentation like inductively coupled plasma-mass spectrometry (ICP-MS) combined with specific sample preparation techniques.

During Processing: Chromium contamination can occur from processing equipment or packaging materials, leading to higher detected levels. For example, stainless steels (the gold standard for use in facilities can falsely elevate the detectable chromium levels due Chromium oxide which resides on the surfaces.

Complex Matrices: Cannabis samples contain organic compounds, cannabinoids, and terpenes that can interfere with heavy metal analysis. Proper sample digestion and matrix removal are crucial for accurate chromium detection.

Moisture Content: Variations in cannabis moisture levels can affect the concentration calculations of heavy metals in dry weight samples, introducing potential inaccuracies.

Equipment Calibration: Differences in the calibration of ICP-MS or atomic absorption spectrometers can result in inconsistent chromium measurements.

Lack of Standardized Limits: Chromium testing guidelines and permissible limits vary widely Some states or countries may not specify limits for chromium or differentiate between its forms.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.
- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

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e. OUT-OF SPECIFICATION (OOS) POLICY

Regulations Proposed by DCP:

Failed Microbiological Testing and Retesting Requirements

- If a cannabis sample does not yield satisfactory results during microbiological testing, the cannabis establishment must follow specific procedures:
    - Enter all analysis and test results into the Cannabis Analytic Tracking System.
    - Dispose of the cannabis sample according to Section 21a-421j-3 of the Regulations of Connecticut State Agencies.
    - Comply with retesting, remediation, and disposal provisions as outlined in Section 3 of Public Act 24-76.

Discussion:

Out-of-Specification (OOS) Policy: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory error

Lack of Retesting Policies: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory errors. This can cost operators tens of thousands of dollars per batch of failed testing.

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

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2. EXTENTION OF P&P TIMEFRAME OR EXPANDED REGULATION FLEXIBILITIES RESPONSIVE TO INDUSTRY CAPABILITIES

Regulations Proposed by DCP:

Discussion: Proposed regulations do not allow for urgent changes to cannabis operations and requirements. This is of great concern as many of the first round of licensees have not opened their businesses yet. This disregards the opportunity for the Department to gather information to guide the operations of these new license types.

P&P Time Frams Recommendations: Regulatory Recommendation: Extend the policies and procedures (P&P) review process for an additional 12 months or include a provision granting the Commissioner the authority to adapt regulations at their discretion based on emerging industry information and developments.

CONNECTICUT CANNABIS CHAMBER OF COMMERCE

3. COMPREHENSIVE SUMMARY OF RECOMMENDATIONS

Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting these recommendations, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.To address these issues, we propose the following recommendations

Heterogeneity Recognition Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Consider stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.

CONNECTICUT CANNABIS CHAMBER OF COMMERCE

- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

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APPENDIX A

A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis

INTRODUCTION: This study was conducted to better understand the variances in testing that can be seen in microbiology and potency test for cannabis flower. This study compares these factors across the batch, within the same sample, and between separate labs,

MATERIALS AND METHODS: A controlled study conducted at two labs analyzed 15 samples in duplicate, yielding 30 data points per lab, per test.

- 30 samples of Cannabis were selected from a single batch
- 2 separate labs received 15 samples of each
- Each lab tested 15 samples for THC and for 15 Micro
- Each lab tested lab tested their individual samples twice

RESULTS: Results confirmed substantial variability in cannabis testing:

- **Total THC Analysis**:
  - Lab 1: 11% range
  - Lab 2: 16% range
  - Duplicate results showed inconsistent outcomes, even for identical samples.
- **Total Yeast and Mold Analysis**:
  - Lab 1: 1,400–1,300,000 cfu/g
  - Lab 2: 1,100–471,000 cfu/g
  - Variability between replicates ranged up to several hundredfold.

DISCUSSION: These findings align with academic research documenting cannabis's inherent heterogeneity. Connecticut mandates batch homogenization before testing—an unfeasible standard given cannabis's natural heterogeneity. Additionally, the natural variability indicates that no single lab test is a cohesive representation of the sample.

CONCLUSION: Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting the recommendations in the above proposal, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.

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Posted Date: 01/10/25 04:00:52 PM
Attachments:
Comment Regarding Proposed Cannabis Regulations .pdf
Comment:
Name: Zachs, Benjamin Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 Incredibly important for our industry to succeed.

Comment Regarding Proposed Cannabis Regulations AU and MM

PRIORITY FOR THE FEEDBACK INCLUDED IN THIS DOCUMENT

1. **Considerations for the Re-evaluation of Laboratory Testing Regulations**
    a. Inherent Heterogenity of Cannabis
    b. Final Form Testing (FFT)
    c. Stability Testing
    d. Chromium Testing
    e. Out-of-Specification (OOS) Policy
    f. Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A)
2. **Extension of P&P Timeline or Expanded Regulation Flexibilities Response to Industry Capabilities**
3. **Comprehensive Summary of Recommendations**

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1. CONSIDERATIONS FOR THE RE-EVALUATION OF LABORATORY TESTING REGULATIONS

Our concerns are based on feedback from the industry, a literature review, and a recent study completed in partnership with a producer and the labs. From our perspective, it is clear that the current testing regulations are a hindrance on accuracy, price, and efficacy.

a. INHERENT HETEROGENITY OF CANNABIS

Regulations Proposed by DCP:

Homogenized Batch Preparation

Section 21a-421j-29(e):
Prior to a cannabis testing laboratory collecting samples for certificate of analysis or stability testing, a cannabis establishment shall:

- Prepare each cannabis batch in its **homogenized, final form**.
- Conduct a visual inspection for foreign matter.
- Ensure consistency and integrity between the batch and the samples taken for testingogenous Batch Sampling**

Section 21a-421j-29(g):
To ensure reliable testing, random samples taken from a cannabis batch must be representative of the **homogeneous batch**. Representative sampling requirements include at least four-tenths of one percent of the batch or specific weights or unit quantities for raw cannabis or cannabis products .

Hod Shelf-Stability Requirements Section 21a-421j-25(a):
Cannabis intended for sale must be **homogeneous** and shelf-stable for a minimum of 60 days after opening without refrigeration. This ensures consistency in cannabinoid and terpenoid concentration within the product.

Definitions of the regs

(8) "Batch" means (1) a specifically identified quantity of cannabis trim and cannabis flower, uniform in character and quality, from the same seed stock or cuttings taken from cannabis plants of the same genotype and phenotype, that has undergone the same propagation and cultivation processes, and harvested within a seventy-two hour period, in the same environment, and cured under the same conditions, or (2) a distinct group of cannabis product, uniform in character and quality, that has been produced in the same environment, under the same conditions, and from the same processes, equipment, and ingredients during the same cycle;

(41) "Homogenous" or "Homogenized" means uniform in cannabinoid and terpenoid concentration;

(68) "Sample" means a portion or part of a batch, the characteristics of which represent, as accurately as possible, the entire batch, allowing for the cannabis testing laboratory testing results of the sample to be generally applied to the entire batch;

Discussion:

Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A) notes a statistically significant variance in microbial and potency results in three methods of evaluation:

- Within the the same cannabis batch
- When retesting the same sample
- When the same batch cannabis is tested in different labs
- Batch homogenization before testing— is an unfeasible standard given cannabis's natural heterogeneity.

Plant Heterogeneity: Cannabis is a complex botanical product with natural variability in composition. Heavy metals, including chromium, may accumulate differently across parts of the plant (e.g., roots, stems, and flowers), making representative sampling difficult.

Inherent Heterogeneity: Cannabis is a natural product with significant variability in cannabinoid and terpene concentrations across different parts of the plant. Even within a single batch, slight differences in moisture content, particle size, or composition can lead to inconsistent test results.

Formulation Variability: Final products like edibles, tinctures, and topicals are often complex formulations that require homogenization for accurate testing. Achieving and verifying this homogenization is difficult, especially for products like infused flower or layered edibles.

Heterogeneity Recognition of Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
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- **Account for the natural variability for results** when setting Laboratory Testing Standards

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b. FINAL FORM TESTING (FFT)

Regulations Proposed by DCP:

Preparation in Final Form: Section 21a-421j-29(e): Before a cannabis testing laboratory collects samples for a certificate of analysis or stability testing:

- The cannabis batch must be prepared in its homogenized, final form.
- A visual inspection for foreign matter is required.
- The entire batch must be placed in final packaging to ensure consistency and integrity between the batch and the sampled product.

Batch Size and Testing: Section 21a-421j-29(g): Representative random samples must be taken from batches prepared in their final form. Sample quantities depend on the batch size to ensure accurate representation and testing.

Isolation of Final Form Batches During Testing: Section 21a-421j-29(h): While a batch is being tested for a certificate of analysis, it must be withheld from use, stored securely, and only released upon satisfactory test results.

Packaging and Labeling: Section 21a-421j-30(f): Cannabis or cannabis products may only be labeled with a product name if their composition matches the registered final form and the cannabinoid/terpenoid profiles fall within 90–110% of the registered values.

Storage and Handling Requirements For All Found in The Regs: Section 21a-421j- 24. Minimum requirements for the storage and handling of cannabis by a producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter. (a) A producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter shall: (1) Maintain all production, manufacturing, handling and storage areas with adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions for cannabis that meet the standards set forth under 21 CFR Part 211 Subpart C except as otherwise expressly permitted by the commissioner, and except that outdoor grow handling and storage areas need only meet the requirements of these policies and procedures;

- Section 21a-421j-25. Cannabis Manufacturing Restrictions. (a) Except as otherwise provided in section 21a-421j-28 of these Policies and Procedures, cannabis permitted for sale to a consumer, qualifying patient or caregiver shall meet the following requirements, and any cannabis not in compliance with this section shall be deemed adulterated:
- (1) Cannabis shall be homogenous and shelf-stable for a minimum of sixty days after opening without refrigeration. (2) Cannabis products shall only be produced and manufactured in compliance with 21 CFR Part 211 Subpart B, (A) using ingredients and components permitted by the U.S. Food and Drug Administration for the specified use in food or food manufacturing pursuant to the Substances Added to Food inventory, if edible, (B) with equipment that meets the standards set forth under 21 CFR Part 211 Subpart D, and (C) in facilities that meet the standards set forth under 21 CFR Part 211 Subpart C.
- (D) Documenting the chain of custody of all cannabis, in compliance with 21 CFR Part 211 Subpart J, which documentation shall include, but not be limited to, the name of each employee that conducts an activity required to be recorded.
- Connecticut Food, Drug and Cosmetic Act, sections 21a91 to 21a-120, inclusive, and sections 21a-151 to 21a-159, inclusive, of the Connecticut General Statutes, regarding bakeries and food manufacturing establishments.
- Section 21a-421j-29. Cannabis Testing Laboratory Processes and Testing. (g) [On or before] Prior to January 1, 2025, the number of random samples, sufficient to ensure a representative sampling, taken from a cannabis batch [must] shall be representative of the

homogenous batch to ensure reliable testing. On or after January 1, 2025, the quantity and number of cannabis samples taken for certificate of analysis testing pursuant to subsection (i) of this section shall be taken at random, sufficient to ensure representative sampling of the corresponding batch. Representative samples shall consist of at least four tenths of one percent of the batch, but in no circumstance less than twenty grams for raw cannabis or, for cannabis products, the number of units required in accordance with the following table:

Discussion: In 2018, under the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), California implemented Final Form Testing but abandoned it in 2020 with Assembly Bill 1470 due to inefficiency and high costs to the detriment of the industry with no added value to consumers or regulators. Assembly Bill 1470 redefined “final form” to mean “the unpackaged product as it will be consumed,” allowing for batch testing of unpackaged products. This shift reduced waste, improved efficiency, and highlighted the failure of final form testing. Packaging can be tested as part of process validation, including the evaluation and qualification of container-closure systems and stability determinations for finished product batches.

- "...In the pharma [industry], you don't test the product in it's final packaging.... but you can be delivered that final form in bulk to test the product...get the COA...release it...then package it."
- "Every sample sent to a lab has to be opened by a lab technician. Multiply this mind-numbing time-losing activity by thousands of samples."
- **Testing in Final Form vs Final Packaging:** https://youtu.be/oNq-bL6Vimk?si=kCCl4xgrJNiY75t1

While FFT intends to that cannabis products meet safety and quality standards, its implementation presents significant challenges, particularly for high-variability products and small businesses. Addressing these issues requires regulatory flexibility, improved testing methodologies, and consideration of alternatives like IBT to balance safety, cost, and efficiency.Final Form Testing (FFT) in cannabis presents several challenges related to practicality, consistency, and cost. These issues stem from the inherent variability in cannabis products, the complexities of testing processes, and logistical constraints. Below is an overview of the primary challenges:

- **Conflicting Recovery Standards**: The state’s recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures.
- **Final Form Testing Intent** is to test the product at the point of consumption. Notably to identify if the package is creating contamination. Packaging can be tested independently for potential contaminates that could bio accumulate.

Increased Opportunity For Error:

- **21 CFR Part 211 Subparts B, C, and D** as referenced the DCPs Proposed Regulations speak repeatedly to the mitigating the opportunity for mixups, and keeping products labeled, and making sure that facilities are structured to accommodate these demands of operation. These newly referenced regulations speak to mix-ups and concerns that they would use to prep in a pharmaceutical facility
- **FFT testing requires operators** to hold on 6-10 weeks of unlabeled product, in secure storage space, that the facilities were not designed to manages. This inherently required operators to act in direct opposition to the **21 CFR Part 211** guidelines.

Costly Process: Testing every individual product in its packaged, "final form" state can significantly increase costs for producers, as each variant and SKU requires separate testing.

Delayed Time Frame For Product To Get To Market: Final form testing requires that every unique product be tested after packaging, which complicates supply chain workflows and slows down the release of products to market.

Randomized Sampling: Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.

Disproportionate Burden on Small Operators: Smaller cannabis businesses often lack the resources to manage the increased costs and operational complexity associated with FFT.

Replicability Issues: Laboratories may produce varying results for identical products due to differences in equipment, methodology, or sample preparation. This lack of standardization complicates regulatory compliance.

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

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c. STABILITY TESTING STANDARDS

Regulations Proposed by DCP:

Stability Testing in Final Packaging

- Section 21a-421j-30(b): Stability testing is mandatory for cannabis products in their final packaging, including:
    a. The first registered batch in each product category.
    b. First batch of each registered beverage, edible product, or vape oil.
    c. Stability testing intervals: 30 and 60 days.
    d. Samples must undergo cannabinoid, heavy metal, and microbial testing.
    e. The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis.

Homogeneity in Final Packaging

- Section 21a-421j-30(e): If stability test results fall outside the acceptable range (90–110%), the label must be updated to reflect the actual composition and expiration date. This ensures that the cannabis or cannabis product in final form matches its registered attribute*s.*

Discussion:

Stability Concerns: FFT often requires that cannabinoid content remains within a specific percentage of the labeled claim over time (e.g., ±10%). Due to the natural degradation of cannabinoids and terpenes during storage, many products fail stability tests despite being safe and effective.

Time Frame: Due to FFT, products may not make it out the door before they need to be submitted for 30 and 60 day stability testing.

Potency Variability with Stability Testing and Conflicting Recovery Standards: The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis. Additionally, the state's recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures."By unnecessarily reporting results to the one-hundredth percentile, some labs created an unrealistic illusion of precision that raises false expectations regarding the degree to which accuracy is possible, given the 20% variation observed."
https://www.canorml.org/business-resources-for-cannabis-brands/how-accurate-is-cannabis-potency-testing/

Packaging Interference: Packaging materials can interact with the product during testing, introducing variables that skew results (e.g., THC adhering to certain plastics).

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Replace stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

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d. CHROMIUM TESTING

Regulations Proposed by DCP:

Section 21a-421j-29(i)(3):

- Cannabis samples must be tested for heavy metals, including chromium, to ensure compliance with the following thresholds:
  - Inhalation Route: ≤ 0.6 µg/g
  - Non-Inhalation Route: ≤ 2.0 µg/g
- These limits ensure the product is safe for consumption or use according to the intended delivery metho*d.*

Discussion: Chromium is not commonly tested in cannabis products across most states. This concern is better addressed through periodic monitoring within a comprehensive Hazard Analysis and Critical Control Points (HACCP) program rather than testing individual products. Such an approach allows for proactive identification and mitigation of contamination risks in cultivation environments.

However, we recognize the unique risks posed by vaporizable cannabis products, where chromium may accumulate in heating elements or delivery systems. These scenarios may require alternative considerations, including targeted testing or material-specific evaluations, to ensure consumer safety.

Differentiation of Chromium Species: Chromium exists in multiple oxidation states, primarily trivalent (essential and less toxic) and hexavalent (highly toxic). Accurately differentiating

between these species requires advanced instrumentation like inductively coupled plasma-mass spectrometry (ICP-MS) combined with specific sample preparation techniques.

During Processing: Chromium contamination can occur from processing equipment or packaging materials, leading to higher detected levels. For example, stainless steels (the gold standard for use in facilities can falsely elevate the detectable chromium levels due Chromium oxide which resides on the surfaces.

Complex Matrices: Cannabis samples contain organic compounds, cannabinoids, and terpenes that can interfere with heavy metal analysis. Proper sample digestion and matrix removal are crucial for accurate chromium detection.

Moisture Content: Variations in cannabis moisture levels can affect the concentration calculations of heavy metals in dry weight samples, introducing potential inaccuracies.

Equipment Calibration: Differences in the calibration of ICP-MS or atomic absorption spectrometers can result in inconsistent chromium measurements.

Lack of Standardized Limits: Chromium testing guidelines and permissible limits vary widely Some states or countries may not specify limits for chromium or differentiate between its forms.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.
- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

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e. OUT-OF SPECIFICATION (OOS) POLICY

Regulations Proposed by DCP:

Failed Microbiological Testing and Retesting Requirements

- If a cannabis sample does not yield satisfactory results during microbiological testing, the cannabis establishment must follow specific procedures:
    - Enter all analysis and test results into the Cannabis Analytic Tracking System.
    - Dispose of the cannabis sample according to Section 21a-421j-3 of the Regulations of Connecticut State Agencies.
    - Comply with retesting, remediation, and disposal provisions as outlined in Section 3 of Public Act 24-76.

Discussion:

Out-of-Specification (OOS) Policy: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory error

Lack of Retesting Policies: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory errors. This can cost operators tens of thousands of dollars per batch of failed testing.

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

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Comment Regarding Proposed Cannabis Regulations .pdf
Comment:
Name: Waldron, Mark Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 Please see below attachment.

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- The entire batch must be placed in final packaging to ensure consistency and integrity between the batch and the sampled product.

Batch Size and Testing: Section 21a-421j-29(g): Representative random samples must be taken from batches prepared in their final form. Sample quantities depend on the batch size to ensure accurate representation and testing.

Isolation of Final Form Batches During Testing: Section 21a-421j-29(h): While a batch is being tested for a certificate of analysis, it must be withheld from use, stored securely, and only released upon satisfactory test results.

Packaging and Labeling: Section 21a-421j-30(f): Cannabis or cannabis products may only be labeled with a product name if their composition matches the registered final form and the cannabinoid/terpenoid profiles fall within 90–110% of the registered values.

Storage and Handling Requirements For All Found in The Regs: Section 21a-421j- 24. Minimum requirements for the storage and handling of cannabis by a producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter. (a) A producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter shall: (1) Maintain all production, manufacturing, handling and storage areas with adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions for cannabis that meet the standards set forth under 21 CFR Part 211 Subpart C except as otherwise expressly permitted by the commissioner, and except that outdoor grow handling and storage areas need only meet the requirements of these policies and procedures;

- Section 21a-421j-25. Cannabis Manufacturing Restrictions. (a) Except as otherwise provided in section 21a-421j-28 of these Policies and Procedures, cannabis permitted for sale to a consumer, qualifying patient or caregiver shall meet the following requirements, and any cannabis not in compliance with this section shall be deemed adulterated:
- (1) Cannabis shall be homogenous and shelf-stable for a minimum of sixty days after opening without refrigeration. (2) Cannabis products shall only be produced and manufactured in compliance with 21 CFR Part 211 Subpart B, (A) using ingredients and components permitted by the U.S. Food and Drug Administration for the specified use in food or food manufacturing pursuant to the Substances Added to Food inventory, if edible, (B) with equipment that meets the standards set forth under 21 CFR Part 211 Subpart D, and (C) in facilities that meet the standards set forth under 21 CFR Part 211 Subpart C.
- (D) Documenting the chain of custody of all cannabis, in compliance with 21 CFR Part 211 Subpart J, which documentation shall include, but not be limited to, the name of each employee that conducts an activity required to be recorded.
- Connecticut Food, Drug and Cosmetic Act, sections 21a91 to 21a-120, inclusive, and sections 21a-151 to 21a-159, inclusive, of the Connecticut General Statutes, regarding bakeries and food manufacturing establishments.
- Section 21a-421j-29. Cannabis Testing Laboratory Processes and Testing. (g) [On or before] Prior to January 1, 2025, the number of random samples, sufficient to ensure a representative sampling, taken from a cannabis batch [must] shall be representative of the

homogenous batch to ensure reliable testing. On or after January 1, 2025, the quantity and number of cannabis samples taken for certificate of analysis testing pursuant to subsection (i) of this section shall be taken at random, sufficient to ensure representative sampling of the corresponding batch. Representative samples shall consist of at least four tenths of one percent of the batch, but in no circumstance less than twenty grams for raw cannabis or, for cannabis products, the number of units required in accordance with the following table:

Discussion: In 2018, under the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), California implemented Final Form Testing but abandoned it in 2020 with Assembly Bill 1470 due to inefficiency and high costs to the detriment of the industry with no added value to consumers or regulators. Assembly Bill 1470 redefined “final form” to mean “the unpackaged product as it will be consumed,” allowing for batch testing of unpackaged products. This shift reduced waste, improved efficiency, and highlighted the failure of final form testing. Packaging can be tested as part of process validation, including the evaluation and qualification of container-closure systems and stability determinations for finished product batches.

- "...In the pharma [industry], you don't test the product in it's final packaging.... but you can be delivered that final form in bulk to test the product...get the COA...release it...then package it."
- "Every sample sent to a lab has to be opened by a lab technician. Multiply this mind-numbing time-losing activity by thousands of samples."
- **Testing in Final Form vs Final Packaging:** https://youtu.be/oNq-bL6Vimk?si=kCCl4xgrJNiY75t1

While FFT intends to that cannabis products meet safety and quality standards, its implementation presents significant challenges, particularly for high-variability products and small businesses. Addressing these issues requires regulatory flexibility, improved testing methodologies, and consideration of alternatives like IBT to balance safety, cost, and efficiency.Final Form Testing (FFT) in cannabis presents several challenges related to practicality, consistency, and cost. These issues stem from the inherent variability in cannabis products, the complexities of testing processes, and logistical constraints. Below is an overview of the primary challenges:

- **Conflicting Recovery Standards**: The state’s recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures.
- **Final Form Testing Intent** is to test the product at the point of consumption. Notably to identify if the package is creating contamination. Packaging can be tested independently for potential contaminates that could bio accumulate.

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- **21 CFR Part 211 Subparts B, C, and D** as referenced the DCPs Proposed Regulations speak repeatedly to the mitigating the opportunity for mixups, and keeping products labeled, and making sure that facilities are structured to accommodate these demands of operation. These newly referenced regulations speak to mix-ups and concerns that they would use to prep in a pharmaceutical facility
- **FFT testing requires operators** to hold on 6-10 weeks of unlabeled product, in secure storage space, that the facilities were not designed to manages. This inherently required operators to act in direct opposition to the **21 CFR Part 211** guidelines.

Costly Process: Testing every individual product in its packaged, "final form" state can significantly increase costs for producers, as each variant and SKU requires separate testing.

Delayed Time Frame For Product To Get To Market: Final form testing requires that every unique product be tested after packaging, which complicates supply chain workflows and slows down the release of products to market.

Randomized Sampling: Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.

Disproportionate Burden on Small Operators: Smaller cannabis businesses often lack the resources to manage the increased costs and operational complexity associated with FFT.

Replicability Issues: Laboratories may produce varying results for identical products due to differences in equipment, methodology, or sample preparation. This lack of standardization complicates regulatory compliance.

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

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c. STABILITY TESTING STANDARDS

Regulations Proposed by DCP:

Stability Testing in Final Packaging

- Section 21a-421j-30(b): Stability testing is mandatory for cannabis products in their final packaging, including:
    a. The first registered batch in each product category.
    b. First batch of each registered beverage, edible product, or vape oil.
    c. Stability testing intervals: 30 and 60 days.
    d. Samples must undergo cannabinoid, heavy metal, and microbial testing.
    e. The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis.

Homogeneity in Final Packaging

- Section 21a-421j-30(e): If stability test results fall outside the acceptable range (90–110%), the label must be updated to reflect the actual composition and expiration date. This ensures that the cannabis or cannabis product in final form matches its registered attribute*s.*

Discussion:

Stability Concerns: FFT often requires that cannabinoid content remains within a specific percentage of the labeled claim over time (e.g., ±10%). Due to the natural degradation of cannabinoids and terpenes during storage, many products fail stability tests despite being safe and effective.

Time Frame: Due to FFT, products may not make it out the door before they need to be submitted for 30 and 60 day stability testing.

Potency Variability with Stability Testing and Conflicting Recovery Standards: The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis. Additionally, the state's recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures."By unnecessarily reporting results to the one-hundredth percentile, some labs created an unrealistic illusion of precision that raises false expectations regarding the degree to which accuracy is possible, given the 20% variation observed."
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Packaging Interference: Packaging materials can interact with the product during testing, introducing variables that skew results (e.g., THC adhering to certain plastics).

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Replace stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

---

d. CHROMIUM TESTING

Regulations Proposed by DCP:

Section 21a-421j-29(i)(3):

- Cannabis samples must be tested for heavy metals, including chromium, to ensure compliance with the following thresholds:
  - Inhalation Route: ≤ 0.6 µg/g
  - Non-Inhalation Route: ≤ 2.0 µg/g
- These limits ensure the product is safe for consumption or use according to the intended delivery metho*d.*

Discussion: Chromium is not commonly tested in cannabis products across most states. This concern is better addressed through periodic monitoring within a comprehensive Hazard Analysis and Critical Control Points (HACCP) program rather than testing individual products. Such an approach allows for proactive identification and mitigation of contamination risks in cultivation environments.

However, we recognize the unique risks posed by vaporizable cannabis products, where chromium may accumulate in heating elements or delivery systems. These scenarios may require alternative considerations, including targeted testing or material-specific evaluations, to ensure consumer safety.

Differentiation of Chromium Species: Chromium exists in multiple oxidation states, primarily trivalent (essential and less toxic) and hexavalent (highly toxic). Accurately differentiating

between these species requires advanced instrumentation like inductively coupled plasma-mass spectrometry (ICP-MS) combined with specific sample preparation techniques.

During Processing: Chromium contamination can occur from processing equipment or packaging materials, leading to higher detected levels. For example, stainless steels (the gold standard for use in facilities can falsely elevate the detectable chromium levels due Chromium oxide which resides on the surfaces.

Complex Matrices: Cannabis samples contain organic compounds, cannabinoids, and terpenes that can interfere with heavy metal analysis. Proper sample digestion and matrix removal are crucial for accurate chromium detection.

Moisture Content: Variations in cannabis moisture levels can affect the concentration calculations of heavy metals in dry weight samples, introducing potential inaccuracies.

Equipment Calibration: Differences in the calibration of ICP-MS or atomic absorption spectrometers can result in inconsistent chromium measurements.

Lack of Standardized Limits: Chromium testing guidelines and permissible limits vary widely Some states or countries may not specify limits for chromium or differentiate between its forms.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.
- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

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e. OUT-OF SPECIFICATION (OOS) POLICY

Regulations Proposed by DCP:

Failed Microbiological Testing and Retesting Requirements

- If a cannabis sample does not yield satisfactory results during microbiological testing, the cannabis establishment must follow specific procedures:
    - Enter all analysis and test results into the Cannabis Analytic Tracking System.
    - Dispose of the cannabis sample according to Section 21a-421j-3 of the Regulations of Connecticut State Agencies.
    - Comply with retesting, remediation, and disposal provisions as outlined in Section 3 of Public Act 24-76.

Discussion:

Out-of-Specification (OOS) Policy: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory error

Lack of Retesting Policies: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory errors. This can cost operators tens of thousands of dollars per batch of failed testing.

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

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2. EXTENTION OF P&P TIMEFRAME OR EXPANDED REGULATION FLEXIBILITIES RESPONSIVE TO INDUSTRY CAPABILITIES

Regulations Proposed by DCP:

Discussion: Proposed regulations do not allow for urgent changes to cannabis operations and requirements. This is of great concern as many of the first round of licensees have not opened their businesses yet. This disregards the opportunity for the Department to gather information to guide the operations of these new license types.

P&P Time Frams Recommendations: Regulatory Recommendation: Extend the policies and procedures (P&P) review process for an additional 12 months or include a provision granting the Commissioner the authority to adapt regulations at their discretion based on emerging industry information and developments.

3. COMPREHENSIVE SUMMARY OF RECOMMENDATIONS

Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting these recommendations, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.To address these issues, we propose the following recommendations

Heterogeneity Recognition Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Consider stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.

- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

P&P Time Frams Recommendations: Regulatory Recommendation: Extend the policies and procedures (P&P) review process for an additional 12 months or include a provision granting the Commissioner the authority to adapt regulations at their discretion based on emerging industry information and developments.

APPENDIX A

A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis

INTRODUCTION: This study was conducted to better understand the variances in testing that can be seen in microbiology and potency test for cannabis flower. This study compares these factors across the batch, within the same sample, and between separate labs,

MATERIALS AND METHODS: A controlled study conducted at two labs analyzed 15 samples in duplicate, yielding 30 data points per lab, per test.

- 30 samples of Cannabis were selected from a single batch
- 2 separate labs received 15 samples of each
- Each lab tested 15 samples for THC and for 15 Micro
- Each lab tested lab tested their individual samples twice

RESULTS: Results confirmed substantial variability in cannabis testing:

- **Total THC Analysis**:
  - Lab 1: 11% range
  - Lab 2: 16% range
  - Duplicate results showed inconsistent outcomes, even for identical samples.
- **Total Yeast and Mold Analysis**:
  - Lab 1: 1,400–1,300,000 cfu/g
  - Lab 2: 1,100–471,000 cfu/g
  - Variability between replicates ranged up to several hundredfold.

DISCUSSION: These findings align with academic research documenting cannabis's inherent heterogeneity. Connecticut mandates batch homogenization before testing—an unfeasible standard given cannabis's natural heterogeneity. Additionally, the natural variability indicates that no single lab test is a cohesive representation of the sample.

CONCLUSION: Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting the recommendations in the above proposal, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.

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Commenter Association: Fine Fettle
Commenter Title: Director of Production Operations
Posted Date:
Attachments:
Comment Regarding Proposed Cannabis Regulations .pdf
Comment:
Name: Hawley, Kevin Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 Attached document in response to the DCP proposed cannabis regulations.

Comment Regarding Proposed Cannabis Regulations AU and MM

PRIORITY FOR THE FEEDBACK INCLUDED IN THIS DOCUMENT

1. **Considerations for the Re-evaluation of Laboratory Testing Regulations**
    a. Inherent Heterogenity of Cannabis
    b. Final Form Testing (FFT)
    c. Stability Testing
    d. Chromium Testing
    e. Out-of-Specification (OOS) Policy
    f. Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A)
2. **Extension of P&P Timeline or Expanded Regulation Flexibilities Response to Industry Capabilities**
3. **Comprehensive Summary of Recommendations**

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1. CONSIDERATIONS FOR THE RE-EVALUATION OF LABORATORY TESTING REGULATIONS

Our concerns are based on feedback from the industry, a literature review, and a recent study completed in partnership with a producer and the labs. From our perspective, it is clear that the current testing regulations are a hindrance on accuracy, price, and efficacy.

a. INHERENT HETEROGENITY OF CANNABIS

Regulations Proposed by DCP:

Homogenized Batch Preparation

Section 21a-421j-29(e):
Prior to a cannabis testing laboratory collecting samples for certificate of analysis or stability testing, a cannabis establishment shall:

- Prepare each cannabis batch in its **homogenized, final form**.
- Conduct a visual inspection for foreign matter.
- Ensure consistency and integrity between the batch and the samples taken for testingogenous Batch Sampling**

Section 21a-421j-29(g):
To ensure reliable testing, random samples taken from a cannabis batch must be representative of the **homogeneous batch**. Representative sampling requirements include at least four-tenths of one percent of the batch or specific weights or unit quantities for raw cannabis or cannabis products .

Hod Shelf-Stability Requirements Section 21a-421j-25(a):
Cannabis intended for sale must be **homogeneous** and shelf-stable for a minimum of 60 days after opening without refrigeration. This ensures consistency in cannabinoid and terpenoid concentration within the product.

Definitions of the regs

(8) "Batch" means (1) a specifically identified quantity of cannabis trim and cannabis flower, uniform in character and quality, from the same seed stock or cuttings taken from cannabis plants of the same genotype and phenotype, that has undergone the same propagation and cultivation processes, and harvested within a seventy-two hour period, in the same environment, and cured under the same conditions, or (2) a distinct group of cannabis product, uniform in character and quality, that has been produced in the same environment, under the same conditions, and from the same processes, equipment, and ingredients during the same cycle;

(41) "Homogenous" or "Homogenized" means uniform in cannabinoid and terpenoid concentration;

(68) "Sample" means a portion or part of a batch, the characteristics of which represent, as accurately as possible, the entire batch, allowing for the cannabis testing laboratory testing results of the sample to be generally applied to the entire batch;

Discussion:

Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A) notes a statistically significant variance in microbial and potency results in three methods of evaluation:

- Within the the same cannabis batch
- When retesting the same sample
- When the same batch cannabis is tested in different labs
- Batch homogenization before testing— is an unfeasible standard given cannabis's natural heterogeneity.

Plant Heterogeneity: Cannabis is a complex botanical product with natural variability in composition. Heavy metals, including chromium, may accumulate differently across parts of the plant (e.g., roots, stems, and flowers), making representative sampling difficult.

Inherent Heterogeneity: Cannabis is a natural product with significant variability in cannabinoid and terpene concentrations across different parts of the plant. Even within a single batch, slight differences in moisture content, particle size, or composition can lead to inconsistent test results.

Formulation Variability: Final products like edibles, tinctures, and topicals are often complex formulations that require homogenization for accurate testing. Achieving and verifying this homogenization is difficult, especially for products like infused flower or layered edibles.

Heterogeneity Recognition of Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

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b. FINAL FORM TESTING (FFT)

Regulations Proposed by DCP:

Preparation in Final Form: Section 21a-421j-29(e): Before a cannabis testing laboratory collects samples for a certificate of analysis or stability testing:

- The cannabis batch must be prepared in its homogenized, final form.
- A visual inspection for foreign matter is required.
- The entire batch must be placed in final packaging to ensure consistency and integrity between the batch and the sampled product.

Batch Size and Testing: Section 21a-421j-29(g): Representative random samples must be taken from batches prepared in their final form. Sample quantities depend on the batch size to ensure accurate representation and testing.

Isolation of Final Form Batches During Testing: Section 21a-421j-29(h): While a batch is being tested for a certificate of analysis, it must be withheld from use, stored securely, and only released upon satisfactory test results.

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- These limits ensure the product is safe for consumption or use according to the intended delivery metho*d.*

Discussion: Chromium is not commonly tested in cannabis products across most states. This concern is better addressed through periodic monitoring within a comprehensive Hazard Analysis and Critical Control Points (HACCP) program rather than testing individual products. Such an approach allows for proactive identification and mitigation of contamination risks in cultivation environments.

However, we recognize the unique risks posed by vaporizable cannabis products, where chromium may accumulate in heating elements or delivery systems. These scenarios may require alternative considerations, including targeted testing or material-specific evaluations, to ensure consumer safety.

Differentiation of Chromium Species: Chromium exists in multiple oxidation states, primarily trivalent (essential and less toxic) and hexavalent (highly toxic). Accurately differentiating

between these species requires advanced instrumentation like inductively coupled plasma-mass spectrometry (ICP-MS) combined with specific sample preparation techniques.

During Processing: Chromium contamination can occur from processing equipment or packaging materials, leading to higher detected levels. For example, stainless steels (the gold standard for use in facilities can falsely elevate the detectable chromium levels due Chromium oxide which resides on the surfaces.

Complex Matrices: Cannabis samples contain organic compounds, cannabinoids, and terpenes that can interfere with heavy metal analysis. Proper sample digestion and matrix removal are crucial for accurate chromium detection.

Moisture Content: Variations in cannabis moisture levels can affect the concentration calculations of heavy metals in dry weight samples, introducing potential inaccuracies.

Equipment Calibration: Differences in the calibration of ICP-MS or atomic absorption spectrometers can result in inconsistent chromium measurements.

Lack of Standardized Limits: Chromium testing guidelines and permissible limits vary widely Some states or countries may not specify limits for chromium or differentiate between its forms.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.
- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

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e. OUT-OF SPECIFICATION (OOS) POLICY

Regulations Proposed by DCP:

Failed Microbiological Testing and Retesting Requirements

- If a cannabis sample does not yield satisfactory results during microbiological testing, the cannabis establishment must follow specific procedures:
    - Enter all analysis and test results into the Cannabis Analytic Tracking System.
    - Dispose of the cannabis sample according to Section 21a-421j-3 of the Regulations of Connecticut State Agencies.
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Discussion:

Out-of-Specification (OOS) Policy: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory error

Lack of Retesting Policies: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory errors. This can cost operators tens of thousands of dollars per batch of failed testing.

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

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2. EXTENTION OF P&P TIMEFRAME OR EXPANDED REGULATION FLEXIBILITIES RESPONSIVE TO INDUSTRY CAPABILITIES

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Discussion: Proposed regulations do not allow for urgent changes to cannabis operations and requirements. This is of great concern as many of the first round of licensees have not opened their businesses yet. This disregards the opportunity for the Department to gather information to guide the operations of these new license types.

P&P Time Frams Recommendations: Regulatory Recommendation: Extend the policies and procedures (P&P) review process for an additional 12 months or include a provision granting the Commissioner the authority to adapt regulations at their discretion based on emerging industry information and developments.

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Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting these recommendations, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.To address these issues, we propose the following recommendations

Heterogeneity Recognition Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

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- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
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- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

Stability Testing Recommendations:

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APPENDIX A

A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis

INTRODUCTION: This study was conducted to better understand the variances in testing that can be seen in microbiology and potency test for cannabis flower. This study compares these factors across the batch, within the same sample, and between separate labs,

MATERIALS AND METHODS: A controlled study conducted at two labs analyzed 15 samples in duplicate, yielding 30 data points per lab, per test.

- 30 samples of Cannabis were selected from a single batch
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RESULTS: Results confirmed substantial variability in cannabis testing:

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  - Lab 1: 11% range
  - Lab 2: 16% range
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  - Lab 1: 1,400–1,300,000 cfu/g
  - Lab 2: 1,100–471,000 cfu/g
  - Variability between replicates ranged up to several hundredfold.

DISCUSSION: These findings align with academic research documenting cannabis's inherent heterogeneity. Connecticut mandates batch homogenization before testing—an unfeasible standard given cannabis's natural heterogeneity. Additionally, the natural variability indicates that no single lab test is a cohesive representation of the sample.

CONCLUSION: Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting the recommendations in the above proposal, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.

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Commenter Title: Citizen
Posted Date: 01/10/25 04:19:27 PM
Comment:
Name: Jannes, John Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 The new Cannabis proposals are truly pathetic from a consumer point of view. CT regulators listened exclusively to unethical multi state operators when drafting the first set of rules and continue to heed the advice of these horrible companies. Those companies are complaining about not making enough money and CT regulators are listening! Why don?t you listen to consumers??? We need competition, not reinforced monopolies! You DECREASED home grow. You made it HARDER for new companies to enter the market, and you PROTECT the companies that are overcharging CT residents for blatantly inferior products and services by any and every metric. Just allow competition and the market will sort itself out. Stop protecting these out of state grifters. It?s embarrassing to be a resident of Connecticut when this kind of legislation counts as consumer protection. CT earns a failing grade yet again. If nothing else, CT regulators are consistent - consistently pathetic when it comes to cannabis regulation.

Comment ID: 23
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Commenter Association: Fine Fettle
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Attachments:
Comment Regarding Proposed Cannabis Regulations .pdf
Comment:
Name: Ray, Kennard Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 Please see attached.

Comment Regarding Proposed Cannabis Regulations AU and MM

PRIORITY FOR THE FEEDBACK INCLUDED IN THIS DOCUMENT

1. **Considerations for the Re-evaluation of Laboratory Testing Regulations**
    a. Inherent Heterogenity of Cannabis
    b. Final Form Testing (FFT)
    c. Stability Testing
    d. Chromium Testing
    e. Out-of-Specification (OOS) Policy
    f. Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A)
2. **Extension of P&P Timeline or Expanded Regulation Flexibilities Response to Industry Capabilities**
3. **Comprehensive Summary of Recommendations**

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1. CONSIDERATIONS FOR THE RE-EVALUATION OF LABORATORY TESTING REGULATIONS

Our concerns are based on feedback from the industry, a literature review, and a recent study completed in partnership with a producer and the labs. From our perspective, it is clear that the current testing regulations are a hindrance on accuracy, price, and efficacy.

a. INHERENT HETEROGENITY OF CANNABIS

Regulations Proposed by DCP:

Homogenized Batch Preparation

Section 21a-421j-29(e):
Prior to a cannabis testing laboratory collecting samples for certificate of analysis or stability testing, a cannabis establishment shall:

- Prepare each cannabis batch in its **homogenized, final form**.
- Conduct a visual inspection for foreign matter.
- Ensure consistency and integrity between the batch and the samples taken for testingogenous Batch Sampling**

Section 21a-421j-29(g):
To ensure reliable testing, random samples taken from a cannabis batch must be representative of the **homogeneous batch**. Representative sampling requirements include at least four-tenths of one percent of the batch or specific weights or unit quantities for raw cannabis or cannabis products .

Hod Shelf-Stability Requirements Section 21a-421j-25(a):
Cannabis intended for sale must be **homogeneous** and shelf-stable for a minimum of 60 days after opening without refrigeration. This ensures consistency in cannabinoid and terpenoid concentration within the product.

Definitions of the regs

(8) "Batch" means (1) a specifically identified quantity of cannabis trim and cannabis flower, uniform in character and quality, from the same seed stock or cuttings taken from cannabis plants of the same genotype and phenotype, that has undergone the same propagation and cultivation processes, and harvested within a seventy-two hour period, in the same environment, and cured under the same conditions, or (2) a distinct group of cannabis product, uniform in character and quality, that has been produced in the same environment, under the same conditions, and from the same processes, equipment, and ingredients during the same cycle;

(41) "Homogenous" or "Homogenized" means uniform in cannabinoid and terpenoid concentration;

(68) "Sample" means a portion or part of a batch, the characteristics of which represent, as accurately as possible, the entire batch, allowing for the cannabis testing laboratory testing results of the sample to be generally applied to the entire batch;

Discussion:

Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A) notes a statistically significant variance in microbial and potency results in three methods of evaluation:

- Within the the same cannabis batch
- When retesting the same sample
- When the same batch cannabis is tested in different labs
- Batch homogenization before testing— is an unfeasible standard given cannabis's natural heterogeneity.

Plant Heterogeneity: Cannabis is a complex botanical product with natural variability in composition. Heavy metals, including chromium, may accumulate differently across parts of the plant (e.g., roots, stems, and flowers), making representative sampling difficult.

Inherent Heterogeneity: Cannabis is a natural product with significant variability in cannabinoid and terpene concentrations across different parts of the plant. Even within a single batch, slight differences in moisture content, particle size, or composition can lead to inconsistent test results.

Formulation Variability: Final products like edibles, tinctures, and topicals are often complex formulations that require homogenization for accurate testing. Achieving and verifying this homogenization is difficult, especially for products like infused flower or layered edibles.

Heterogeneity Recognition of Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

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b. FINAL FORM TESTING (FFT)

Regulations Proposed by DCP:

Preparation in Final Form: Section 21a-421j-29(e): Before a cannabis testing laboratory collects samples for a certificate of analysis or stability testing:

- The cannabis batch must be prepared in its homogenized, final form.
- A visual inspection for foreign matter is required.
- The entire batch must be placed in final packaging to ensure consistency and integrity between the batch and the sampled product.

Batch Size and Testing: Section 21a-421j-29(g): Representative random samples must be taken from batches prepared in their final form. Sample quantities depend on the batch size to ensure accurate representation and testing.

Isolation of Final Form Batches During Testing: Section 21a-421j-29(h): While a batch is being tested for a certificate of analysis, it must be withheld from use, stored securely, and only released upon satisfactory test results.

Packaging and Labeling: Section 21a-421j-30(f): Cannabis or cannabis products may only be labeled with a product name if their composition matches the registered final form and the cannabinoid/terpenoid profiles fall within 90–110% of the registered values.

Storage and Handling Requirements For All Found in The Regs: Section 21a-421j- 24. Minimum requirements for the storage and handling of cannabis by a producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter. (a) A producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter shall: (1) Maintain all production, manufacturing, handling and storage areas with adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions for cannabis that meet the standards set forth under 21 CFR Part 211 Subpart C except as otherwise expressly permitted by the commissioner, and except that outdoor grow handling and storage areas need only meet the requirements of these policies and procedures;

- Section 21a-421j-25. Cannabis Manufacturing Restrictions. (a) Except as otherwise provided in section 21a-421j-28 of these Policies and Procedures, cannabis permitted for sale to a consumer, qualifying patient or caregiver shall meet the following requirements, and any cannabis not in compliance with this section shall be deemed adulterated:
- (1) Cannabis shall be homogenous and shelf-stable for a minimum of sixty days after opening without refrigeration. (2) Cannabis products shall only be produced and manufactured in compliance with 21 CFR Part 211 Subpart B, (A) using ingredients and components permitted by the U.S. Food and Drug Administration for the specified use in food or food manufacturing pursuant to the Substances Added to Food inventory, if edible, (B) with equipment that meets the standards set forth under 21 CFR Part 211 Subpart D, and (C) in facilities that meet the standards set forth under 21 CFR Part 211 Subpart C.
- (D) Documenting the chain of custody of all cannabis, in compliance with 21 CFR Part 211 Subpart J, which documentation shall include, but not be limited to, the name of each employee that conducts an activity required to be recorded.
- Connecticut Food, Drug and Cosmetic Act, sections 21a91 to 21a-120, inclusive, and sections 21a-151 to 21a-159, inclusive, of the Connecticut General Statutes, regarding bakeries and food manufacturing establishments.
- Section 21a-421j-29. Cannabis Testing Laboratory Processes and Testing. (g) [On or before] Prior to January 1, 2025, the number of random samples, sufficient to ensure a representative sampling, taken from a cannabis batch [must] shall be representative of the

homogenous batch to ensure reliable testing. On or after January 1, 2025, the quantity and number of cannabis samples taken for certificate of analysis testing pursuant to subsection (i) of this section shall be taken at random, sufficient to ensure representative sampling of the corresponding batch. Representative samples shall consist of at least four tenths of one percent of the batch, but in no circumstance less than twenty grams for raw cannabis or, for cannabis products, the number of units required in accordance with the following table:

Discussion: In 2018, under the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), California implemented Final Form Testing but abandoned it in 2020 with Assembly Bill 1470 due to inefficiency and high costs to the detriment of the industry with no added value to consumers or regulators. Assembly Bill 1470 redefined “final form” to mean “the unpackaged product as it will be consumed,” allowing for batch testing of unpackaged products. This shift reduced waste, improved efficiency, and highlighted the failure of final form testing. Packaging can be tested as part of process validation, including the evaluation and qualification of container-closure systems and stability determinations for finished product batches.

- "...In the pharma [industry], you don't test the product in it's final packaging.... but you can be delivered that final form in bulk to test the product...get the COA...release it...then package it."
- "Every sample sent to a lab has to be opened by a lab technician. Multiply this mind-numbing time-losing activity by thousands of samples."
- **Testing in Final Form vs Final Packaging:** https://youtu.be/oNq-bL6Vimk?si=kCCl4xgrJNiY75t1

While FFT intends to that cannabis products meet safety and quality standards, its implementation presents significant challenges, particularly for high-variability products and small businesses. Addressing these issues requires regulatory flexibility, improved testing methodologies, and consideration of alternatives like IBT to balance safety, cost, and efficiency.Final Form Testing (FFT) in cannabis presents several challenges related to practicality, consistency, and cost. These issues stem from the inherent variability in cannabis products, the complexities of testing processes, and logistical constraints. Below is an overview of the primary challenges:

- **Conflicting Recovery Standards**: The state’s recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures.
- **Final Form Testing Intent** is to test the product at the point of consumption. Notably to identify if the package is creating contamination. Packaging can be tested independently for potential contaminates that could bio accumulate.

Increased Opportunity For Error:

- **21 CFR Part 211 Subparts B, C, and D** as referenced the DCPs Proposed Regulations speak repeatedly to the mitigating the opportunity for mixups, and keeping products labeled, and making sure that facilities are structured to accommodate these demands of operation. These newly referenced regulations speak to mix-ups and concerns that they would use to prep in a pharmaceutical facility
- **FFT testing requires operators** to hold on 6-10 weeks of unlabeled product, in secure storage space, that the facilities were not designed to manages. This inherently required operators to act in direct opposition to the **21 CFR Part 211** guidelines.

Costly Process: Testing every individual product in its packaged, "final form" state can significantly increase costs for producers, as each variant and SKU requires separate testing.

Delayed Time Frame For Product To Get To Market: Final form testing requires that every unique product be tested after packaging, which complicates supply chain workflows and slows down the release of products to market.

Randomized Sampling: Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.

Disproportionate Burden on Small Operators: Smaller cannabis businesses often lack the resources to manage the increased costs and operational complexity associated with FFT.

Replicability Issues: Laboratories may produce varying results for identical products due to differences in equipment, methodology, or sample preparation. This lack of standardization complicates regulatory compliance.

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
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- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

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c. STABILITY TESTING STANDARDS

Regulations Proposed by DCP:

Stability Testing in Final Packaging

- Section 21a-421j-30(b): Stability testing is mandatory for cannabis products in their final packaging, including:
    a. The first registered batch in each product category.
    b. First batch of each registered beverage, edible product, or vape oil.
    c. Stability testing intervals: 30 and 60 days.
    d. Samples must undergo cannabinoid, heavy metal, and microbial testing.
    e. The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis.

Homogeneity in Final Packaging

- Section 21a-421j-30(e): If stability test results fall outside the acceptable range (90–110%), the label must be updated to reflect the actual composition and expiration date. This ensures that the cannabis or cannabis product in final form matches its registered attribute*s.*

Discussion:

Stability Concerns: FFT often requires that cannabinoid content remains within a specific percentage of the labeled claim over time (e.g., ±10%). Due to the natural degradation of cannabinoids and terpenes during storage, many products fail stability tests despite being safe and effective.

Time Frame: Due to FFT, products may not make it out the door before they need to be submitted for 30 and 60 day stability testing.

Potency Variability with Stability Testing and Conflicting Recovery Standards: The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis. Additionally, the state's recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures."By unnecessarily reporting results to the one-hundredth percentile, some labs created an unrealistic illusion of precision that raises false expectations regarding the degree to which accuracy is possible, given the 20% variation observed."
https://www.canorml.org/business-resources-for-cannabis-brands/how-accurate-is-cannabis-potency-testing/

Packaging Interference: Packaging materials can interact with the product during testing, introducing variables that skew results (e.g., THC adhering to certain plastics).

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Replace stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

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d. CHROMIUM TESTING

Regulations Proposed by DCP:

Section 21a-421j-29(i)(3):

- Cannabis samples must be tested for heavy metals, including chromium, to ensure compliance with the following thresholds:
  - Inhalation Route: ≤ 0.6 µg/g
  - Non-Inhalation Route: ≤ 2.0 µg/g
- These limits ensure the product is safe for consumption or use according to the intended delivery metho*d.*

Discussion: Chromium is not commonly tested in cannabis products across most states. This concern is better addressed through periodic monitoring within a comprehensive Hazard Analysis and Critical Control Points (HACCP) program rather than testing individual products. Such an approach allows for proactive identification and mitigation of contamination risks in cultivation environments.

However, we recognize the unique risks posed by vaporizable cannabis products, where chromium may accumulate in heating elements or delivery systems. These scenarios may require alternative considerations, including targeted testing or material-specific evaluations, to ensure consumer safety.

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Posted Date: 01/10/25 04:20:36 PM
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01 10 2025 CMCC Comments.pdf
Comment:
Name: Werstler, Ethan Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 Please accept these comments from the Connecticut Medical Cannabis Council. Please see attachment.

Comments on PR 2024-053
By: Connecticut Medical Cannabis Council
January 10, 2025

The Connecticut Medical Cannabis Council is comprised of the four producers of medical marijuana and adult use cannabis. We bring years of experience to the cannabis space and have been involved with the Connecticut programs from Day One. Our members, and their principal locations, include: Curaleaf (Simsbury), Green Thumb Industries (West Haven), Theraplant (Watertown) and Verano (Rocky Hill). We are providing comments in this document on Proposed Regulation 2024-053.

It is in the spirit of continued cooperation with the Department of Consumer Protection that we outline proposed revisions to the regulation. We believe our ideas will help improve the program so that medical marijuana patients and adult-use consumers have the highest quality product, safely tested, at the lowest price.

With regard to PR 2024-053, *Regulation of Adult Use Cannabis*, we suggest a number of specific revisions.

Section 21a-421j-2, Reportable Events

We are required to notify DCP in cases of suspected diversion or theft of the product. The regulation is silent as to an important aspect of the process. We request specific language be added to make it clear that a licensee (in our case the producer or their retail stores) has first right to investigate and interview an individual suspected of wrongdoing. There have been instances where a producer reported one such instance and was told by DCP staff verbally that they may not interview the employee and must, instead, turn the matter over to them. Our companies have highly qualified asset protection, loss prevention and humans resource teams that are trained to do this very type of investigation. We believe it should be clear that we have first right of action in these investigations. As such, we would request that appropriate text be inserted in this section to accomplish that. One option in subsection (a) would be to delete “suspected” and insert “confirmed”.

Section 21a-421j-6, License Records; Furnishing Information; Audits

Subsection (d) speaks to DCP’s ability to conduct on-site inspections. We believe this is an appropriate requirement and work hard to provide your inspectors with access to the areas of our facilities that are requested. The end-result of inspections is not a standardized process, however. Some inspectors will go over issues of concern verbally with our site managers, while others

might not do so. Some inspectors will leave us with a written document outlining the reasons for the inspection and what they found in this regard, others do not. CMCC members request that specific language be added in this section that requires, at the conclusion of each inspection, a debrief in which the inspector provides the site manager with a written form or report of the results. This should outline if a corrective action is required. The form should be standardized and include a section where the licensee can dispute the inspector's findings. Our members spend a great deal of time accommodating DCP inspections, and we will always make this a priority. A standardized written document also protects DCP.

The following text is suggested: "After an inspection in which a violation of Chapter 420h or implementing regulations is observed or a violation is otherwise determined to have occurred, the Department shall issue a deficiency statement citing every violation identified, including a description of the violation and a reference to the statute or regulation violated, a copy of which shall be left with or sent to the cannabis establishment within 24 hours of the inspection."

Section 21a-421j-30, Product Name Testing and Registration

Our members believe the current structure on product registration could exacerbate production delays due to the product registration process. Many of their labeling lines are designed to be performed on empty containers. If they are required to package well in advance of labeling (which is contingent upon product registration approval), they will lose that automation function entirely. Several pieces of machinery are designed to label empty containers, which cannot occur if they package prior to labeling. The product registration process requires each "batch" to be represented as a "SKU." This disallows variable data on the labels, such as packaging date, if the batch requires multiple days of packaging. Product registration is also an administrative choke point that causes further delays while the producers wait for approval.

Section 21a-421j-29, Cannabis Testing Laboratory Processing and Testing

CMCC would suggest that there should be an allowance for product variance. For example, if we label a product as 5 mg but it comes back as 5.2 mg, that slight variance should be permitted.

We would reiterate our belief that there should be a scientific basis for testing requirements or before guidance is given on remediation. For a testing example, only Hexavalent Chromium (Vl) has proven carcinogenic with negative health effects, while Trivalent, also tested, does not need to be because there is no proven negative health effects.

Regarding testing in final packaging, we are required to package an entire batch for testing. A better approach is for the lab to select the specific samples and we would then package those.

Section a-421j-31, Cannabis Packaging Requirements

Sending out oil, concentrates, and flower in final packaging creates redundant testing on the same batch of material and increases manufacturing costs that then drives up costs for consumers. For example, vape carts and flower jars filled ½ way or filled completely use the same parent batch. The same oil or flower can be used for carts/pods/disposables or whole flower/pre-rolls but would require separate tests even though it is the same parent batch.

If the decision is to require testing of gummies/edibles & pre-rolls in final packaging, we would support that. However, testing the same gummies/edibles or pre-rolls in different-sized packaging is redundant. We believe an appropriate solution is to test bulk oil & bulk flower.

Bulk/unmarked containers create room for human error, miscounts, in inefficient operations. Testing in final packaging makes any sort of packaging automation nearly impossible. This will cause testing delays and slow down product to the market. Our suggestion is to require stability testing for every batch instead of requiring everything in final packaging when testing is pulled.

ASTM Alternative Symbol

To combat the patchwork of inconsistent state "universal" symbols that have been adopted across the country, many states are adopting the ASTM International Intoxicating Cannabinoid Product Symbol (IICPS), so that a consistent symbol will be used nationwide and even globally as more states and countries enact cannabis regulations. As Connecticut has already created its own symbol, we request that the regulations in Section 21a-421j-32(a)(3) be amended to allow the IICPS as an alternate symbol.

Accounts Receivable

One of the challenges in the cannabis industry is an inability to collect accounts receivable. Other states have taken steps to ensure that operators have options to ensure that they are not exploited by predatory businesses. We recommend that DCP follow the example set by these states and enact regulations to address delinquent payments. (e.g. New York Office of Cannabis Management: https://cannabis.ny.gov/system/files/documents/2024/03/delinquent-payments-guidance.pdf).

Product Categories

Product categories for Adult Use Cannabis manufacturing should be increased in order to create more variety for the adult consumers. The desire for these products will require businesses to invest in new equipment. This would in turn increase product variety for medical consumers as has been a concern expressed by DCP. Equipment investments are unlikely if product sales are limited to a small number of consumers

Stakeholder Advisory Committee

We do believe we can bring much to the table when it comes to the science of cannabis. Collectively, we do business throughout the nation in each and every state that has medical and consumer cannabis programs and have scientists on staff who are recognized for their expertise. We propose that language be added to the regulation to create a "Stakeholder Advisory Committee," which would advise DCP on the latest science and technology in the field. It is true that we have done this to a limited degree over the years through informal conversations with DCP. We believe it is time to formalize the process, however. Regularly scheduled meetings with everyone around the table will enhance the cannabis endeavor. The final call on what happens with the ideas that come from the SAC would rest with DCP. We have no doubt that this structure will bring new cutting-edge findings that DCP might not be aware of. A number of states, Colorado, Florida, Massachusetts, Pennsylvania and Rhode Island have utilized this type

of stakeholder role. We would also note the medical marijuana program includes a Physician's Board to advise and recommend on a range of policies.

Waiver

The proposed regulation gives broad authority to the commissioner to waive program requirements when there is a need to do so. For instance, the commissioner may waive rules that pertain to testing, transaction limits or security requirements. CMCC would request the creation of an additional waiver concerning the time limit by which an equity joint venture is created pursuant to Section 21a-420m and Section 21a-420u of the general statutes. Our proposal would be to give the commissioner the discretion to extend the 14-month limit on agreements to 24 months. We believe the additional ten months will significantly benefit social equity applicants who might not otherwise meet the tighter 14-month deadline.

Thank you for considering these comments from the Connecticut Medical Cannabis Council.

Comment ID: 25
First Name: Nicholas
Last Name: Cimadon
Commenter Email: nick@getsoundview.com
Comment Input Method: Portal
Commenter Association: SoundView
Commenter Title: CEO
Posted Date: 01/10/25 04:26:56 PM
Attachments:
Comment Regarding Proposed Cannabis Regulations .pdf
Comment:
Name: Cimadon, Nicholas Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 Please see the attached PDF with the recommended changes to the current cannabis testing requirements.

Comment Regarding Proposed Cannabis Regulations AU and MM

PRIORITY FOR THE FEEDBACK INCLUDED IN THIS DOCUMENT

1. **Considerations for the Re-evaluation of Laboratory Testing Regulations**
    a. Inherent Heterogenity of Cannabis
    b. Final Form Testing (FFT)
    c. Stability Testing
    d. Chromium Testing
    e. Out-of-Specification (OOS) Policy
    f. Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A)
2. **Extension of P&P Timeline or Expanded Regulation Flexibilities Response to Industry Capabilities**
3. **Comprehensive Summary of Recommendations**

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1. CONSIDERATIONS FOR THE RE-EVALUATION OF LABORATORY TESTING REGULATIONS

Our concerns are based on feedback from the industry, a literature review, and a recent study completed in partnership with a producer and the labs. From our perspective, it is clear that the current testing regulations are a hindrance on accuracy, price, and efficacy.

a. INHERENT HETEROGENITY OF CANNABIS

Regulations Proposed by DCP:

Homogenized Batch Preparation

Section 21a-421j-29(e):
Prior to a cannabis testing laboratory collecting samples for certificate of analysis or stability testing, a cannabis establishment shall:

- Prepare each cannabis batch in its **homogenized, final form**.
- Conduct a visual inspection for foreign matter.
- Ensure consistency and integrity between the batch and the samples taken for testingogenous Batch Sampling**

Section 21a-421j-29(g):
To ensure reliable testing, random samples taken from a cannabis batch must be representative of the **homogeneous batch**. Representative sampling requirements include at least four-tenths of one percent of the batch or specific weights or unit quantities for raw cannabis or cannabis products .

Hod Shelf-Stability Requirements Section 21a-421j-25(a):
Cannabis intended for sale must be **homogeneous** and shelf-stable for a minimum of 60 days after opening without refrigeration. This ensures consistency in cannabinoid and terpenoid concentration within the product.

Definitions of the regs

(8) "Batch" means (1) a specifically identified quantity of cannabis trim and cannabis flower, uniform in character and quality, from the same seed stock or cuttings taken from cannabis plants of the same genotype and phenotype, that has undergone the same propagation and cultivation processes, and harvested within a seventy-two hour period, in the same environment, and cured under the same conditions, or (2) a distinct group of cannabis product, uniform in character and quality, that has been produced in the same environment, under the same conditions, and from the same processes, equipment, and ingredients during the same cycle;

(41) "Homogenous" or "Homogenized" means uniform in cannabinoid and terpenoid concentration;

(68) "Sample" means a portion or part of a batch, the characteristics of which represent, as accurately as possible, the entire batch, allowing for the cannabis testing laboratory testing results of the sample to be generally applied to the entire batch;

Discussion:

Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A) notes a statistically significant variance in microbial and potency results in three methods of evaluation:

- Within the the same cannabis batch
- When retesting the same sample
- When the same batch cannabis is tested in different labs
- Batch homogenization before testing— is an unfeasible standard given cannabis's natural heterogeneity.

Plant Heterogeneity: Cannabis is a complex botanical product with natural variability in composition. Heavy metals, including chromium, may accumulate differently across parts of the plant (e.g., roots, stems, and flowers), making representative sampling difficult.

Inherent Heterogeneity: Cannabis is a natural product with significant variability in cannabinoid and terpene concentrations across different parts of the plant. Even within a single batch, slight differences in moisture content, particle size, or composition can lead to inconsistent test results.

Formulation Variability: Final products like edibles, tinctures, and topicals are often complex formulations that require homogenization for accurate testing. Achieving and verifying this homogenization is difficult, especially for products like infused flower or layered edibles.

Heterogeneity Recognition of Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

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b. FINAL FORM TESTING (FFT)

Regulations Proposed by DCP:

Preparation in Final Form: Section 21a-421j-29(e): Before a cannabis testing laboratory collects samples for a certificate of analysis or stability testing:

- The cannabis batch must be prepared in its homogenized, final form.
- A visual inspection for foreign matter is required.
- The entire batch must be placed in final packaging to ensure consistency and integrity between the batch and the sampled product.

Batch Size and Testing: Section 21a-421j-29(g): Representative random samples must be taken from batches prepared in their final form. Sample quantities depend on the batch size to ensure accurate representation and testing.

Isolation of Final Form Batches During Testing: Section 21a-421j-29(h): While a batch is being tested for a certificate of analysis, it must be withheld from use, stored securely, and only released upon satisfactory test results.

Packaging and Labeling: Section 21a-421j-30(f): Cannabis or cannabis products may only be labeled with a product name if their composition matches the registered final form and the cannabinoid/terpenoid profiles fall within 90–110% of the registered values.

Storage and Handling Requirements For All Found in The Regs: Section 21a-421j- 24. Minimum requirements for the storage and handling of cannabis by a producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter. (a) A producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter shall: (1) Maintain all production, manufacturing, handling and storage areas with adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions for cannabis that meet the standards set forth under 21 CFR Part 211 Subpart C except as otherwise expressly permitted by the commissioner, and except that outdoor grow handling and storage areas need only meet the requirements of these policies and procedures;

- Section 21a-421j-25. Cannabis Manufacturing Restrictions. (a) Except as otherwise provided in section 21a-421j-28 of these Policies and Procedures, cannabis permitted for sale to a consumer, qualifying patient or caregiver shall meet the following requirements, and any cannabis not in compliance with this section shall be deemed adulterated:
- (1) Cannabis shall be homogenous and shelf-stable for a minimum of sixty days after opening without refrigeration. (2) Cannabis products shall only be produced and manufactured in compliance with 21 CFR Part 211 Subpart B, (A) using ingredients and components permitted by the U.S. Food and Drug Administration for the specified use in food or food manufacturing pursuant to the Substances Added to Food inventory, if edible, (B) with equipment that meets the standards set forth under 21 CFR Part 211 Subpart D, and (C) in facilities that meet the standards set forth under 21 CFR Part 211 Subpart C.
- (D) Documenting the chain of custody of all cannabis, in compliance with 21 CFR Part 211 Subpart J, which documentation shall include, but not be limited to, the name of each employee that conducts an activity required to be recorded.
- Connecticut Food, Drug and Cosmetic Act, sections 21a91 to 21a-120, inclusive, and sections 21a-151 to 21a-159, inclusive, of the Connecticut General Statutes, regarding bakeries and food manufacturing establishments.
- Section 21a-421j-29. Cannabis Testing Laboratory Processes and Testing. (g) [On or before] Prior to January 1, 2025, the number of random samples, sufficient to ensure a representative sampling, taken from a cannabis batch [must] shall be representative of the

homogenous batch to ensure reliable testing. On or after January 1, 2025, the quantity and number of cannabis samples taken for certificate of analysis testing pursuant to subsection (i) of this section shall be taken at random, sufficient to ensure representative sampling of the corresponding batch. Representative samples shall consist of at least four tenths of one percent of the batch, but in no circumstance less than twenty grams for raw cannabis or, for cannabis products, the number of units required in accordance with the following table:

Discussion: In 2018, under the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), California implemented Final Form Testing but abandoned it in 2020 with Assembly Bill 1470 due to inefficiency and high costs to the detriment of the industry with no added value to consumers or regulators. Assembly Bill 1470 redefined “final form” to mean “the unpackaged product as it will be consumed,” allowing for batch testing of unpackaged products. This shift reduced waste, improved efficiency, and highlighted the failure of final form testing. Packaging can be tested as part of process validation, including the evaluation and qualification of container-closure systems and stability determinations for finished product batches.

- "...In the pharma [industry], you don't test the product in it's final packaging.... but you can be delivered that final form in bulk to test the product...get the COA...release it...then package it."
- "Every sample sent to a lab has to be opened by a lab technician. Multiply this mind-numbing time-losing activity by thousands of samples."
- **Testing in Final Form vs Final Packaging:** https://youtu.be/oNq-bL6Vimk?si=kCCl4xgrJNiY75t1

While FFT intends to that cannabis products meet safety and quality standards, its implementation presents significant challenges, particularly for high-variability products and small businesses. Addressing these issues requires regulatory flexibility, improved testing methodologies, and consideration of alternatives like IBT to balance safety, cost, and efficiency.Final Form Testing (FFT) in cannabis presents several challenges related to practicality, consistency, and cost. These issues stem from the inherent variability in cannabis products, the complexities of testing processes, and logistical constraints. Below is an overview of the primary challenges:

- **Conflicting Recovery Standards**: The state’s recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures.
- **Final Form Testing Intent** is to test the product at the point of consumption. Notably to identify if the package is creating contamination. Packaging can be tested independently for potential contaminates that could bio accumulate.

Increased Opportunity For Error:

- **21 CFR Part 211 Subparts B, C, and D** as referenced the DCPs Proposed Regulations speak repeatedly to the mitigating the opportunity for mixups, and keeping products labeled, and making sure that facilities are structured to accommodate these demands of operation. These newly referenced regulations speak to mix-ups and concerns that they would use to prep in a pharmaceutical facility
- **FFT testing requires operators** to hold on 6-10 weeks of unlabeled product, in secure storage space, that the facilities were not designed to manages. This inherently required operators to act in direct opposition to the **21 CFR Part 211** guidelines.

Costly Process: Testing every individual product in its packaged, "final form" state can significantly increase costs for producers, as each variant and SKU requires separate testing.

Delayed Time Frame For Product To Get To Market: Final form testing requires that every unique product be tested after packaging, which complicates supply chain workflows and slows down the release of products to market.

Randomized Sampling: Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.

Disproportionate Burden on Small Operators: Smaller cannabis businesses often lack the resources to manage the increased costs and operational complexity associated with FFT.

Replicability Issues: Laboratories may produce varying results for identical products due to differences in equipment, methodology, or sample preparation. This lack of standardization complicates regulatory compliance.

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

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c. STABILITY TESTING STANDARDS

Regulations Proposed by DCP:

Stability Testing in Final Packaging

- Section 21a-421j-30(b): Stability testing is mandatory for cannabis products in their final packaging, including:
    a. The first registered batch in each product category.
    b. First batch of each registered beverage, edible product, or vape oil.
    c. Stability testing intervals: 30 and 60 days.
    d. Samples must undergo cannabinoid, heavy metal, and microbial testing.
    e. The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis.

Homogeneity in Final Packaging

- Section 21a-421j-30(e): If stability test results fall outside the acceptable range (90–110%), the label must be updated to reflect the actual composition and expiration date. This ensures that the cannabis or cannabis product in final form matches its registered attribute*s.*

Discussion:

Stability Concerns: FFT often requires that cannabinoid content remains within a specific percentage of the labeled claim over time (e.g., ±10%). Due to the natural degradation of cannabinoids and terpenes during storage, many products fail stability tests despite being safe and effective.

Time Frame: Due to FFT, products may not make it out the door before they need to be submitted for 30 and 60 day stability testing.

Potency Variability with Stability Testing and Conflicting Recovery Standards: The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis. Additionally, the state's recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures."By unnecessarily reporting results to the one-hundredth percentile, some labs created an unrealistic illusion of precision that raises false expectations regarding the degree to which accuracy is possible, given the 20% variation observed."
https://www.canorml.org/business-resources-for-cannabis-brands/how-accurate-is-cannabis-potency-testing/

Packaging Interference: Packaging materials can interact with the product during testing, introducing variables that skew results (e.g., THC adhering to certain plastics).

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Replace stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

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d. CHROMIUM TESTING

Regulations Proposed by DCP:

Section 21a-421j-29(i)(3):

- Cannabis samples must be tested for heavy metals, including chromium, to ensure compliance with the following thresholds:
  - Inhalation Route: ≤ 0.6 µg/g
  - Non-Inhalation Route: ≤ 2.0 µg/g
- These limits ensure the product is safe for consumption or use according to the intended delivery metho*d.*

Discussion: Chromium is not commonly tested in cannabis products across most states. This concern is better addressed through periodic monitoring within a comprehensive Hazard Analysis and Critical Control Points (HACCP) program rather than testing individual products. Such an approach allows for proactive identification and mitigation of contamination risks in cultivation environments.

However, we recognize the unique risks posed by vaporizable cannabis products, where chromium may accumulate in heating elements or delivery systems. These scenarios may require alternative considerations, including targeted testing or material-specific evaluations, to ensure consumer safety.

Differentiation of Chromium Species: Chromium exists in multiple oxidation states, primarily trivalent (essential and less toxic) and hexavalent (highly toxic). Accurately differentiating

between these species requires advanced instrumentation like inductively coupled plasma-mass spectrometry (ICP-MS) combined with specific sample preparation techniques.

During Processing: Chromium contamination can occur from processing equipment or packaging materials, leading to higher detected levels. For example, stainless steels (the gold standard for use in facilities can falsely elevate the detectable chromium levels due Chromium oxide which resides on the surfaces.

Complex Matrices: Cannabis samples contain organic compounds, cannabinoids, and terpenes that can interfere with heavy metal analysis. Proper sample digestion and matrix removal are crucial for accurate chromium detection.

Moisture Content: Variations in cannabis moisture levels can affect the concentration calculations of heavy metals in dry weight samples, introducing potential inaccuracies.

Equipment Calibration: Differences in the calibration of ICP-MS or atomic absorption spectrometers can result in inconsistent chromium measurements.

Lack of Standardized Limits: Chromium testing guidelines and permissible limits vary widely Some states or countries may not specify limits for chromium or differentiate between its forms.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.
- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

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e. OUT-OF SPECIFICATION (OOS) POLICY

Regulations Proposed by DCP:

Failed Microbiological Testing and Retesting Requirements

- If a cannabis sample does not yield satisfactory results during microbiological testing, the cannabis establishment must follow specific procedures:
    - Enter all analysis and test results into the Cannabis Analytic Tracking System.
    - Dispose of the cannabis sample according to Section 21a-421j-3 of the Regulations of Connecticut State Agencies.
    - Comply with retesting, remediation, and disposal provisions as outlined in Section 3 of Public Act 24-76.

Discussion:

Out-of-Specification (OOS) Policy: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory error

Lack of Retesting Policies: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory errors. This can cost operators tens of thousands of dollars per batch of failed testing.

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

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2. EXTENTION OF P&P TIMEFRAME OR EXPANDED REGULATION FLEXIBILITIES RESPONSIVE TO INDUSTRY CAPABILITIES

Regulations Proposed by DCP:

Discussion: Proposed regulations do not allow for urgent changes to cannabis operations and requirements. This is of great concern as many of the first round of licensees have not opened their businesses yet. This disregards the opportunity for the Department to gather information to guide the operations of these new license types.

P&P Time Frams Recommendations: Regulatory Recommendation: Extend the policies and procedures (P&P) review process for an additional 12 months or include a provision granting the Commissioner the authority to adapt regulations at their discretion based on emerging industry information and developments.

3. COMPREHENSIVE SUMMARY OF RECOMMENDATIONS

Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting these recommendations, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.To address these issues, we propose the following recommendations

Heterogeneity Recognition Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
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Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
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APPENDIX A

A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis

INTRODUCTION: This study was conducted to better understand the variances in testing that can be seen in microbiology and potency test for cannabis flower. This study compares these factors across the batch, within the same sample, and between separate labs,

MATERIALS AND METHODS: A controlled study conducted at two labs analyzed 15 samples in duplicate, yielding 30 data points per lab, per test.

- 30 samples of Cannabis were selected from a single batch
- 2 separate labs received 15 samples of each
- Each lab tested 15 samples for THC and for 15 Micro
- Each lab tested lab tested their individual samples twice

RESULTS: Results confirmed substantial variability in cannabis testing:

- **Total THC Analysis**:
  - Lab 1: 11% range
  - Lab 2: 16% range
  - Duplicate results showed inconsistent outcomes, even for identical samples.
- **Total Yeast and Mold Analysis**:
  - Lab 1: 1,400–1,300,000 cfu/g
  - Lab 2: 1,100–471,000 cfu/g
  - Variability between replicates ranged up to several hundredfold.

DISCUSSION: These findings align with academic research documenting cannabis's inherent heterogeneity. Connecticut mandates batch homogenization before testing—an unfeasible standard given cannabis's natural heterogeneity. Additionally, the natural variability indicates that no single lab test is a cohesive representation of the sample.

CONCLUSION: Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting the recommendations in the above proposal, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.

Comment ID: 26
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Comment Input Method: Portal
Commenter Association: Earl Baker - Micro Cultivator
Commenter Title: COO
Posted Date: 01/10/25 04:28:41 PM
Attachments:
Comment Regarding Proposed Cannabis Regulations .pdf
Comment:
Name: Motola, Kyle Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 This is my recommendation / feedback for the proposed 2025 cannabis regulations

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- Ensure consistency and integrity between the batch and the samples taken for testingogenous Batch Sampling**

Section 21a-421j-29(g):
To ensure reliable testing, random samples taken from a cannabis batch must be representative of the **homogeneous batch**. Representative sampling requirements include at least four-tenths of one percent of the batch or specific weights or unit quantities for raw cannabis or cannabis products .

Hod Shelf-Stability Requirements Section 21a-421j-25(a):
Cannabis intended for sale must be **homogeneous** and shelf-stable for a minimum of 60 days after opening without refrigeration. This ensures consistency in cannabinoid and terpenoid concentration within the product.

Definitions of the regs

(8) "Batch" means (1) a specifically identified quantity of cannabis trim and cannabis flower, uniform in character and quality, from the same seed stock or cuttings taken from cannabis plants of the same genotype and phenotype, that has undergone the same propagation and cultivation processes, and harvested within a seventy-two hour period, in the same environment, and cured under the same conditions, or (2) a distinct group of cannabis product, uniform in character and quality, that has been produced in the same environment, under the same conditions, and from the same processes, equipment, and ingredients during the same cycle;

(41) "Homogenous" or "Homogenized" means uniform in cannabinoid and terpenoid concentration;

(68) "Sample" means a portion or part of a batch, the characteristics of which represent, as accurately as possible, the entire batch, allowing for the cannabis testing laboratory testing results of the sample to be generally applied to the entire batch;

Discussion:

Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A) notes a statistically significant variance in microbial and potency results in three methods of evaluation:

- Within the the same cannabis batch
- When retesting the same sample
- When the same batch cannabis is tested in different labs
- Batch homogenization before testing— is an unfeasible standard given cannabis's natural heterogeneity.

Plant Heterogeneity: Cannabis is a complex botanical product with natural variability in composition. Heavy metals, including chromium, may accumulate differently across parts of the plant (e.g., roots, stems, and flowers), making representative sampling difficult.

Inherent Heterogeneity: Cannabis is a natural product with significant variability in cannabinoid and terpene concentrations across different parts of the plant. Even within a single batch, slight differences in moisture content, particle size, or composition can lead to inconsistent test results.

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Heterogeneity Recognition of Recommendations:

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- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

---

b. FINAL FORM TESTING (FFT)

Regulations Proposed by DCP:

Preparation in Final Form: Section 21a-421j-29(e): Before a cannabis testing laboratory collects samples for a certificate of analysis or stability testing:

- The cannabis batch must be prepared in its homogenized, final form.
- A visual inspection for foreign matter is required.
- The entire batch must be placed in final packaging to ensure consistency and integrity between the batch and the sampled product.

Batch Size and Testing: Section 21a-421j-29(g): Representative random samples must be taken from batches prepared in their final form. Sample quantities depend on the batch size to ensure accurate representation and testing.

Isolation of Final Form Batches During Testing: Section 21a-421j-29(h): While a batch is being tested for a certificate of analysis, it must be withheld from use, stored securely, and only released upon satisfactory test results.

Packaging and Labeling: Section 21a-421j-30(f): Cannabis or cannabis products may only be labeled with a product name if their composition matches the registered final form and the cannabinoid/terpenoid profiles fall within 90–110% of the registered values.

Storage and Handling Requirements For All Found in The Regs: Section 21a-421j- 24. Minimum requirements for the storage and handling of cannabis by a producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter. (a) A producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter shall: (1) Maintain all production, manufacturing, handling and storage areas with adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions for cannabis that meet the standards set forth under 21 CFR Part 211 Subpart C except as otherwise expressly permitted by the commissioner, and except that outdoor grow handling and storage areas need only meet the requirements of these policies and procedures;

- Section 21a-421j-25. Cannabis Manufacturing Restrictions. (a) Except as otherwise provided in section 21a-421j-28 of these Policies and Procedures, cannabis permitted for sale to a consumer, qualifying patient or caregiver shall meet the following requirements, and any cannabis not in compliance with this section shall be deemed adulterated:
- (1) Cannabis shall be homogenous and shelf-stable for a minimum of sixty days after opening without refrigeration. (2) Cannabis products shall only be produced and manufactured in compliance with 21 CFR Part 211 Subpart B, (A) using ingredients and components permitted by the U.S. Food and Drug Administration for the specified use in food or food manufacturing pursuant to the Substances Added to Food inventory, if edible, (B) with equipment that meets the standards set forth under 21 CFR Part 211 Subpart D, and (C) in facilities that meet the standards set forth under 21 CFR Part 211 Subpart C.
- (D) Documenting the chain of custody of all cannabis, in compliance with 21 CFR Part 211 Subpart J, which documentation shall include, but not be limited to, the name of each employee that conducts an activity required to be recorded.
- Connecticut Food, Drug and Cosmetic Act, sections 21a91 to 21a-120, inclusive, and sections 21a-151 to 21a-159, inclusive, of the Connecticut General Statutes, regarding bakeries and food manufacturing establishments.
- Section 21a-421j-29. Cannabis Testing Laboratory Processes and Testing. (g) [On or before] Prior to January 1, 2025, the number of random samples, sufficient to ensure a representative sampling, taken from a cannabis batch [must] shall be representative of the

homogenous batch to ensure reliable testing. On or after January 1, 2025, the quantity and number of cannabis samples taken for certificate of analysis testing pursuant to subsection (i) of this section shall be taken at random, sufficient to ensure representative sampling of the corresponding batch. Representative samples shall consist of at least four tenths of one percent of the batch, but in no circumstance less than twenty grams for raw cannabis or, for cannabis products, the number of units required in accordance with the following table:

Discussion: In 2018, under the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), California implemented Final Form Testing but abandoned it in 2020 with Assembly Bill 1470 due to inefficiency and high costs to the detriment of the industry with no added value to consumers or regulators. Assembly Bill 1470 redefined “final form” to mean “the unpackaged product as it will be consumed,” allowing for batch testing of unpackaged products. This shift reduced waste, improved efficiency, and highlighted the failure of final form testing. Packaging can be tested as part of process validation, including the evaluation and qualification of container-closure systems and stability determinations for finished product batches.

- "...In the pharma [industry], you don't test the product in it's final packaging.... but you can be delivered that final form in bulk to test the product...get the COA...release it...then package it."
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While FFT intends to that cannabis products meet safety and quality standards, its implementation presents significant challenges, particularly for high-variability products and small businesses. Addressing these issues requires regulatory flexibility, improved testing methodologies, and consideration of alternatives like IBT to balance safety, cost, and efficiency.Final Form Testing (FFT) in cannabis presents several challenges related to practicality, consistency, and cost. These issues stem from the inherent variability in cannabis products, the complexities of testing processes, and logistical constraints. Below is an overview of the primary challenges:

- **Conflicting Recovery Standards**: The state’s recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures.
- **Final Form Testing Intent** is to test the product at the point of consumption. Notably to identify if the package is creating contamination. Packaging can be tested independently for potential contaminates that could bio accumulate.

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Costly Process: Testing every individual product in its packaged, "final form" state can significantly increase costs for producers, as each variant and SKU requires separate testing.

Delayed Time Frame For Product To Get To Market: Final form testing requires that every unique product be tested after packaging, which complicates supply chain workflows and slows down the release of products to market.

Randomized Sampling: Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.

Disproportionate Burden on Small Operators: Smaller cannabis businesses often lack the resources to manage the increased costs and operational complexity associated with FFT.

Replicability Issues: Laboratories may produce varying results for identical products due to differences in equipment, methodology, or sample preparation. This lack of standardization complicates regulatory compliance.

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

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c. STABILITY TESTING STANDARDS

Regulations Proposed by DCP:

Stability Testing in Final Packaging

- Section 21a-421j-30(b): Stability testing is mandatory for cannabis products in their final packaging, including:
    a. The first registered batch in each product category.
    b. First batch of each registered beverage, edible product, or vape oil.
    c. Stability testing intervals: 30 and 60 days.
    d. Samples must undergo cannabinoid, heavy metal, and microbial testing.
    e. The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis.

Homogeneity in Final Packaging

- Section 21a-421j-30(e): If stability test results fall outside the acceptable range (90–110%), the label must be updated to reflect the actual composition and expiration date. This ensures that the cannabis or cannabis product in final form matches its registered attribute*s.*

Discussion:

Stability Concerns: FFT often requires that cannabinoid content remains within a specific percentage of the labeled claim over time (e.g., ±10%). Due to the natural degradation of cannabinoids and terpenes during storage, many products fail stability tests despite being safe and effective.

Time Frame: Due to FFT, products may not make it out the door before they need to be submitted for 30 and 60 day stability testing.

Potency Variability with Stability Testing and Conflicting Recovery Standards: The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis. Additionally, the state's recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures."By unnecessarily reporting results to the one-hundredth percentile, some labs created an unrealistic illusion of precision that raises false expectations regarding the degree to which accuracy is possible, given the 20% variation observed."
https://www.canorml.org/business-resources-for-cannabis-brands/how-accurate-is-cannabis-potency-testing/

Packaging Interference: Packaging materials can interact with the product during testing, introducing variables that skew results (e.g., THC adhering to certain plastics).

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Replace stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

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d. CHROMIUM TESTING

Regulations Proposed by DCP:

Section 21a-421j-29(i)(3):

- Cannabis samples must be tested for heavy metals, including chromium, to ensure compliance with the following thresholds:
  - Inhalation Route: ≤ 0.6 µg/g
  - Non-Inhalation Route: ≤ 2.0 µg/g
- These limits ensure the product is safe for consumption or use according to the intended delivery metho*d.*

Discussion: Chromium is not commonly tested in cannabis products across most states. This concern is better addressed through periodic monitoring within a comprehensive Hazard Analysis and Critical Control Points (HACCP) program rather than testing individual products. Such an approach allows for proactive identification and mitigation of contamination risks in cultivation environments.

However, we recognize the unique risks posed by vaporizable cannabis products, where chromium may accumulate in heating elements or delivery systems. These scenarios may require alternative considerations, including targeted testing or material-specific evaluations, to ensure consumer safety.

Differentiation of Chromium Species: Chromium exists in multiple oxidation states, primarily trivalent (essential and less toxic) and hexavalent (highly toxic). Accurately differentiating

between these species requires advanced instrumentation like inductively coupled plasma-mass spectrometry (ICP-MS) combined with specific sample preparation techniques.

During Processing: Chromium contamination can occur from processing equipment or packaging materials, leading to higher detected levels. For example, stainless steels (the gold standard for use in facilities can falsely elevate the detectable chromium levels due Chromium oxide which resides on the surfaces.

Complex Matrices: Cannabis samples contain organic compounds, cannabinoids, and terpenes that can interfere with heavy metal analysis. Proper sample digestion and matrix removal are crucial for accurate chromium detection.

Moisture Content: Variations in cannabis moisture levels can affect the concentration calculations of heavy metals in dry weight samples, introducing potential inaccuracies.

Equipment Calibration: Differences in the calibration of ICP-MS or atomic absorption spectrometers can result in inconsistent chromium measurements.

Lack of Standardized Limits: Chromium testing guidelines and permissible limits vary widely Some states or countries may not specify limits for chromium or differentiate between its forms.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.
- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

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e. OUT-OF SPECIFICATION (OOS) POLICY

Regulations Proposed by DCP:

Failed Microbiological Testing and Retesting Requirements

- If a cannabis sample does not yield satisfactory results during microbiological testing, the cannabis establishment must follow specific procedures:
    - Enter all analysis and test results into the Cannabis Analytic Tracking System.
    - Dispose of the cannabis sample according to Section 21a-421j-3 of the Regulations of Connecticut State Agencies.
    - Comply with retesting, remediation, and disposal provisions as outlined in Section 3 of Public Act 24-76.

Discussion:

Out-of-Specification (OOS) Policy: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory error

Lack of Retesting Policies: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory errors. This can cost operators tens of thousands of dollars per batch of failed testing.

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

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2. EXTENTION OF P&P TIMEFRAME OR EXPANDED REGULATION FLEXIBILITIES RESPONSIVE TO INDUSTRY CAPABILITIES

Regulations Proposed by DCP:

Discussion: Proposed regulations do not allow for urgent changes to cannabis operations and requirements. This is of great concern as many of the first round of licensees have not opened their businesses yet. This disregards the opportunity for the Department to gather information to guide the operations of these new license types.

P&P Time Frams Recommendations: Regulatory Recommendation: Extend the policies and procedures (P&P) review process for an additional 12 months or include a provision granting the Commissioner the authority to adapt regulations at their discretion based on emerging industry information and developments.

3. COMPREHENSIVE SUMMARY OF RECOMMENDATIONS

Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting these recommendations, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.To address these issues, we propose the following recommendations

Heterogeneity Recognition Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
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APPENDIX A

A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis

INTRODUCTION: This study was conducted to better understand the variances in testing that can be seen in microbiology and potency test for cannabis flower. This study compares these factors across the batch, within the same sample, and between separate labs,

MATERIALS AND METHODS: A controlled study conducted at two labs analyzed 15 samples in duplicate, yielding 30 data points per lab, per test.

- 30 samples of Cannabis were selected from a single batch
- 2 separate labs received 15 samples of each
- Each lab tested 15 samples for THC and for 15 Micro
- Each lab tested lab tested their individual samples twice

RESULTS: Results confirmed substantial variability in cannabis testing:

- **Total THC Analysis**:
  - Lab 1: 11% range
  - Lab 2: 16% range
  - Duplicate results showed inconsistent outcomes, even for identical samples.
- **Total Yeast and Mold Analysis**:
  - Lab 1: 1,400–1,300,000 cfu/g
  - Lab 2: 1,100–471,000 cfu/g
  - Variability between replicates ranged up to several hundredfold.

DISCUSSION: These findings align with academic research documenting cannabis's inherent heterogeneity. Connecticut mandates batch homogenization before testing—an unfeasible standard given cannabis's natural heterogeneity. Additionally, the natural variability indicates that no single lab test is a cohesive representation of the sample.

CONCLUSION: Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting the recommendations in the above proposal, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.

Comment ID: 27
First Name: Carl
Last Name: Tirella
Commenter Email: carl@budrcannabis.com
Comment Input Method: Portal
Commenter Association: Budr Cannabis
Commenter Title: Founder
Posted Date: 01/10/25 04:29:25 PM
Attachments:
Comment Regarding Proposed Cannabis Regulations .pdf
Comment:
Name: Tirella, Carl Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 See attachment. For the good of the industry.

Comment Regarding Proposed Cannabis Regulations AU and MM

PRIORITY FOR THE FEEDBACK INCLUDED IN THIS DOCUMENT

1. **Considerations for the Re-evaluation of Laboratory Testing Regulations**
    a. Inherent Heterogenity of Cannabis
    b. Final Form Testing (FFT)
    c. Stability Testing
    d. Chromium Testing
    e. Out-of-Specification (OOS) Policy
    f. Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A)
2. **Extension of P&P Timeline or Expanded Regulation Flexibilities Response to Industry Capabilities**
3. **Comprehensive Summary of Recommendations**

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1. CONSIDERATIONS FOR THE RE-EVALUATION OF LABORATORY TESTING REGULATIONS

Our concerns are based on feedback from the industry, a literature review, and a recent study completed in partnership with a producer and the labs. From our perspective, it is clear that the current testing regulations are a hindrance on accuracy, price, and efficacy.

a. INHERENT HETEROGENITY OF CANNABIS

Regulations Proposed by DCP:

Homogenized Batch Preparation

Section 21a-421j-29(e):
Prior to a cannabis testing laboratory collecting samples for certificate of analysis or stability testing, a cannabis establishment shall:

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- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

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c. STABILITY TESTING STANDARDS

Regulations Proposed by DCP:

Stability Testing in Final Packaging

- Section 21a-421j-30(b): Stability testing is mandatory for cannabis products in their final packaging, including:
    a. The first registered batch in each product category.
    b. First batch of each registered beverage, edible product, or vape oil.
    c. Stability testing intervals: 30 and 60 days.
    d. Samples must undergo cannabinoid, heavy metal, and microbial testing.
    e. The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis.

Homogeneity in Final Packaging

- Section 21a-421j-30(e): If stability test results fall outside the acceptable range (90–110%), the label must be updated to reflect the actual composition and expiration date. This ensures that the cannabis or cannabis product in final form matches its registered attribute*s.*

Discussion:

Stability Concerns: FFT often requires that cannabinoid content remains within a specific percentage of the labeled claim over time (e.g., ±10%). Due to the natural degradation of cannabinoids and terpenes during storage, many products fail stability tests despite being safe and effective.

Time Frame: Due to FFT, products may not make it out the door before they need to be submitted for 30 and 60 day stability testing.

Potency Variability with Stability Testing and Conflicting Recovery Standards: The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis. Additionally, the state's recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures."By unnecessarily reporting results to the one-hundredth percentile, some labs created an unrealistic illusion of precision that raises false expectations regarding the degree to which accuracy is possible, given the 20% variation observed."
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Packaging Interference: Packaging materials can interact with the product during testing, introducing variables that skew results (e.g., THC adhering to certain plastics).

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Replace stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

---

d. CHROMIUM TESTING

Regulations Proposed by DCP:

Section 21a-421j-29(i)(3):

- Cannabis samples must be tested for heavy metals, including chromium, to ensure compliance with the following thresholds:
  - Inhalation Route: ≤ 0.6 µg/g
  - Non-Inhalation Route: ≤ 2.0 µg/g
- These limits ensure the product is safe for consumption or use according to the intended delivery metho*d.*

Discussion: Chromium is not commonly tested in cannabis products across most states. This concern is better addressed through periodic monitoring within a comprehensive Hazard Analysis and Critical Control Points (HACCP) program rather than testing individual products. Such an approach allows for proactive identification and mitigation of contamination risks in cultivation environments.

However, we recognize the unique risks posed by vaporizable cannabis products, where chromium may accumulate in heating elements or delivery systems. These scenarios may require alternative considerations, including targeted testing or material-specific evaluations, to ensure consumer safety.

Differentiation of Chromium Species: Chromium exists in multiple oxidation states, primarily trivalent (essential and less toxic) and hexavalent (highly toxic). Accurately differentiating

between these species requires advanced instrumentation like inductively coupled plasma-mass spectrometry (ICP-MS) combined with specific sample preparation techniques.

During Processing: Chromium contamination can occur from processing equipment or packaging materials, leading to higher detected levels. For example, stainless steels (the gold standard for use in facilities can falsely elevate the detectable chromium levels due Chromium oxide which resides on the surfaces.

Complex Matrices: Cannabis samples contain organic compounds, cannabinoids, and terpenes that can interfere with heavy metal analysis. Proper sample digestion and matrix removal are crucial for accurate chromium detection.

Moisture Content: Variations in cannabis moisture levels can affect the concentration calculations of heavy metals in dry weight samples, introducing potential inaccuracies.

Equipment Calibration: Differences in the calibration of ICP-MS or atomic absorption spectrometers can result in inconsistent chromium measurements.

Lack of Standardized Limits: Chromium testing guidelines and permissible limits vary widely Some states or countries may not specify limits for chromium or differentiate between its forms.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.
- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

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e. OUT-OF SPECIFICATION (OOS) POLICY

Regulations Proposed by DCP:

Failed Microbiological Testing and Retesting Requirements

- If a cannabis sample does not yield satisfactory results during microbiological testing, the cannabis establishment must follow specific procedures:
    - Enter all analysis and test results into the Cannabis Analytic Tracking System.
    - Dispose of the cannabis sample according to Section 21a-421j-3 of the Regulations of Connecticut State Agencies.
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Discussion:

Out-of-Specification (OOS) Policy: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory error

Lack of Retesting Policies: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory errors. This can cost operators tens of thousands of dollars per batch of failed testing.

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

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2. EXTENTION OF P&P TIMEFRAME OR EXPANDED REGULATION FLEXIBILITIES RESPONSIVE TO INDUSTRY CAPABILITIES

Regulations Proposed by DCP:

Discussion: Proposed regulations do not allow for urgent changes to cannabis operations and requirements. This is of great concern as many of the first round of licensees have not opened their businesses yet. This disregards the opportunity for the Department to gather information to guide the operations of these new license types.

P&P Time Frams Recommendations: Regulatory Recommendation: Extend the policies and procedures (P&P) review process for an additional 12 months or include a provision granting the Commissioner the authority to adapt regulations at their discretion based on emerging industry information and developments.

3. COMPREHENSIVE SUMMARY OF RECOMMENDATIONS

Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting these recommendations, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.To address these issues, we propose the following recommendations

Heterogeneity Recognition Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

FFT Recommendations:

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APPENDIX A

A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis

INTRODUCTION: This study was conducted to better understand the variances in testing that can be seen in microbiology and potency test for cannabis flower. This study compares these factors across the batch, within the same sample, and between separate labs,

MATERIALS AND METHODS: A controlled study conducted at two labs analyzed 15 samples in duplicate, yielding 30 data points per lab, per test.

- 30 samples of Cannabis were selected from a single batch
- 2 separate labs received 15 samples of each
- Each lab tested 15 samples for THC and for 15 Micro
- Each lab tested lab tested their individual samples twice

RESULTS: Results confirmed substantial variability in cannabis testing:

- **Total THC Analysis**:
  - Lab 1: 11% range
  - Lab 2: 16% range
  - Duplicate results showed inconsistent outcomes, even for identical samples.
- **Total Yeast and Mold Analysis**:
  - Lab 1: 1,400–1,300,000 cfu/g
  - Lab 2: 1,100–471,000 cfu/g
  - Variability between replicates ranged up to several hundredfold.

DISCUSSION: These findings align with academic research documenting cannabis's inherent heterogeneity. Connecticut mandates batch homogenization before testing—an unfeasible standard given cannabis's natural heterogeneity. Additionally, the natural variability indicates that no single lab test is a cohesive representation of the sample.

CONCLUSION: Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting the recommendations in the above proposal, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.

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Comment Input Method: Portal
Commenter Association: Earl Baker - Micro Cultivator
Commenter Title: Trim manager
Posted Date: 01/10/25 04:37:34 PM
Attachments:
Comment Regarding Proposed Cannabis Regulations .pdf
Comment:
Name: Chialastri, Tanner Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 Some of the regulations imposed in the field have been overbearing and hinder the work flow making our jobs harder than they have to be, their are many changes to help production flow and industry standards

Comment Regarding Proposed Cannabis Regulations AU and MM

PRIORITY FOR THE FEEDBACK INCLUDED IN THIS DOCUMENT

1. **Considerations for the Re-evaluation of Laboratory Testing Regulations**
    a. Inherent Heterogenity of Cannabis
    b. Final Form Testing (FFT)
    c. Stability Testing
    d. Chromium Testing
    e. Out-of-Specification (OOS) Policy
    f. Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A)
2. **Extension of P&P Timeline or Expanded Regulation Flexibilities Response to Industry Capabilities**
3. **Comprehensive Summary of Recommendations**

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1. CONSIDERATIONS FOR THE RE-EVALUATION OF LABORATORY TESTING REGULATIONS

Our concerns are based on feedback from the industry, a literature review, and a recent study completed in partnership with a producer and the labs. From our perspective, it is clear that the current testing regulations are a hindrance on accuracy, price, and efficacy.

a. INHERENT HETEROGENITY OF CANNABIS

Regulations Proposed by DCP:

Homogenized Batch Preparation

Section 21a-421j-29(e):
Prior to a cannabis testing laboratory collecting samples for certificate of analysis or stability testing, a cannabis establishment shall:

- Prepare each cannabis batch in its **homogenized, final form**.
- Conduct a visual inspection for foreign matter.
- Ensure consistency and integrity between the batch and the samples taken for testingogenous Batch Sampling**

Section 21a-421j-29(g):
To ensure reliable testing, random samples taken from a cannabis batch must be representative of the **homogeneous batch**. Representative sampling requirements include at least four-tenths of one percent of the batch or specific weights or unit quantities for raw cannabis or cannabis products .

Hod Shelf-Stability Requirements Section 21a-421j-25(a):
Cannabis intended for sale must be **homogeneous** and shelf-stable for a minimum of 60 days after opening without refrigeration. This ensures consistency in cannabinoid and terpenoid concentration within the product.

Definitions of the regs

(8) "Batch" means (1) a specifically identified quantity of cannabis trim and cannabis flower, uniform in character and quality, from the same seed stock or cuttings taken from cannabis plants of the same genotype and phenotype, that has undergone the same propagation and cultivation processes, and harvested within a seventy-two hour period, in the same environment, and cured under the same conditions, or (2) a distinct group of cannabis product, uniform in character and quality, that has been produced in the same environment, under the same conditions, and from the same processes, equipment, and ingredients during the same cycle;

(41) "Homogenous" or "Homogenized" means uniform in cannabinoid and terpenoid concentration;

(68) "Sample" means a portion or part of a batch, the characteristics of which represent, as accurately as possible, the entire batch, allowing for the cannabis testing laboratory testing results of the sample to be generally applied to the entire batch;

Discussion:

Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A) notes a statistically significant variance in microbial and potency results in three methods of evaluation:

- Within the the same cannabis batch
- When retesting the same sample
- When the same batch cannabis is tested in different labs
- Batch homogenization before testing— is an unfeasible standard given cannabis's natural heterogeneity.

Plant Heterogeneity: Cannabis is a complex botanical product with natural variability in composition. Heavy metals, including chromium, may accumulate differently across parts of the plant (e.g., roots, stems, and flowers), making representative sampling difficult.

Inherent Heterogeneity: Cannabis is a natural product with significant variability in cannabinoid and terpene concentrations across different parts of the plant. Even within a single batch, slight differences in moisture content, particle size, or composition can lead to inconsistent test results.

Formulation Variability: Final products like edibles, tinctures, and topicals are often complex formulations that require homogenization for accurate testing. Achieving and verifying this homogenization is difficult, especially for products like infused flower or layered edibles.

Heterogeneity Recognition of Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

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b. FINAL FORM TESTING (FFT)

Regulations Proposed by DCP:

Preparation in Final Form: Section 21a-421j-29(e): Before a cannabis testing laboratory collects samples for a certificate of analysis or stability testing:

- The cannabis batch must be prepared in its homogenized, final form.
- A visual inspection for foreign matter is required.
- The entire batch must be placed in final packaging to ensure consistency and integrity between the batch and the sampled product.

Batch Size and Testing: Section 21a-421j-29(g): Representative random samples must be taken from batches prepared in their final form. Sample quantities depend on the batch size to ensure accurate representation and testing.

Isolation of Final Form Batches During Testing: Section 21a-421j-29(h): While a batch is being tested for a certificate of analysis, it must be withheld from use, stored securely, and only released upon satisfactory test results.

Packaging and Labeling: Section 21a-421j-30(f): Cannabis or cannabis products may only be labeled with a product name if their composition matches the registered final form and the cannabinoid/terpenoid profiles fall within 90–110% of the registered values.

Storage and Handling Requirements For All Found in The Regs: Section 21a-421j- 24. Minimum requirements for the storage and handling of cannabis by a producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter. (a) A producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter shall: (1) Maintain all production, manufacturing, handling and storage areas with adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions for cannabis that meet the standards set forth under 21 CFR Part 211 Subpart C except as otherwise expressly permitted by the commissioner, and except that outdoor grow handling and storage areas need only meet the requirements of these policies and procedures;

- Section 21a-421j-25. Cannabis Manufacturing Restrictions. (a) Except as otherwise provided in section 21a-421j-28 of these Policies and Procedures, cannabis permitted for sale to a consumer, qualifying patient or caregiver shall meet the following requirements, and any cannabis not in compliance with this section shall be deemed adulterated:
- (1) Cannabis shall be homogenous and shelf-stable for a minimum of sixty days after opening without refrigeration. (2) Cannabis products shall only be produced and manufactured in compliance with 21 CFR Part 211 Subpart B, (A) using ingredients and components permitted by the U.S. Food and Drug Administration for the specified use in food or food manufacturing pursuant to the Substances Added to Food inventory, if edible, (B) with equipment that meets the standards set forth under 21 CFR Part 211 Subpart D, and (C) in facilities that meet the standards set forth under 21 CFR Part 211 Subpart C.
- (D) Documenting the chain of custody of all cannabis, in compliance with 21 CFR Part 211 Subpart J, which documentation shall include, but not be limited to, the name of each employee that conducts an activity required to be recorded.
- Connecticut Food, Drug and Cosmetic Act, sections 21a91 to 21a-120, inclusive, and sections 21a-151 to 21a-159, inclusive, of the Connecticut General Statutes, regarding bakeries and food manufacturing establishments.
- Section 21a-421j-29. Cannabis Testing Laboratory Processes and Testing. (g) [On or before] Prior to January 1, 2025, the number of random samples, sufficient to ensure a representative sampling, taken from a cannabis batch [must] shall be representative of the

homogenous batch to ensure reliable testing. On or after January 1, 2025, the quantity and number of cannabis samples taken for certificate of analysis testing pursuant to subsection (i) of this section shall be taken at random, sufficient to ensure representative sampling of the corresponding batch. Representative samples shall consist of at least four tenths of one percent of the batch, but in no circumstance less than twenty grams for raw cannabis or, for cannabis products, the number of units required in accordance with the following table:

Discussion: In 2018, under the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), California implemented Final Form Testing but abandoned it in 2020 with Assembly Bill 1470 due to inefficiency and high costs to the detriment of the industry with no added value to consumers or regulators. Assembly Bill 1470 redefined “final form” to mean “the unpackaged product as it will be consumed,” allowing for batch testing of unpackaged products. This shift reduced waste, improved efficiency, and highlighted the failure of final form testing. Packaging can be tested as part of process validation, including the evaluation and qualification of container-closure systems and stability determinations for finished product batches.

- "...In the pharma [industry], you don't test the product in it's final packaging.... but you can be delivered that final form in bulk to test the product...get the COA...release it...then package it."
- "Every sample sent to a lab has to be opened by a lab technician. Multiply this mind-numbing time-losing activity by thousands of samples."
- **Testing in Final Form vs Final Packaging:** https://youtu.be/oNq-bL6Vimk?si=kCCl4xgrJNiY75t1

While FFT intends to that cannabis products meet safety and quality standards, its implementation presents significant challenges, particularly for high-variability products and small businesses. Addressing these issues requires regulatory flexibility, improved testing methodologies, and consideration of alternatives like IBT to balance safety, cost, and efficiency.Final Form Testing (FFT) in cannabis presents several challenges related to practicality, consistency, and cost. These issues stem from the inherent variability in cannabis products, the complexities of testing processes, and logistical constraints. Below is an overview of the primary challenges:

- **Conflicting Recovery Standards**: The state’s recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures.
- **Final Form Testing Intent** is to test the product at the point of consumption. Notably to identify if the package is creating contamination. Packaging can be tested independently for potential contaminates that could bio accumulate.

Increased Opportunity For Error:

- **21 CFR Part 211 Subparts B, C, and D** as referenced the DCPs Proposed Regulations speak repeatedly to the mitigating the opportunity for mixups, and keeping products labeled, and making sure that facilities are structured to accommodate these demands of operation. These newly referenced regulations speak to mix-ups and concerns that they would use to prep in a pharmaceutical facility
- **FFT testing requires operators** to hold on 6-10 weeks of unlabeled product, in secure storage space, that the facilities were not designed to manages. This inherently required operators to act in direct opposition to the **21 CFR Part 211** guidelines.

Costly Process: Testing every individual product in its packaged, "final form" state can significantly increase costs for producers, as each variant and SKU requires separate testing.

Delayed Time Frame For Product To Get To Market: Final form testing requires that every unique product be tested after packaging, which complicates supply chain workflows and slows down the release of products to market.

Randomized Sampling: Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.

Disproportionate Burden on Small Operators: Smaller cannabis businesses often lack the resources to manage the increased costs and operational complexity associated with FFT.

Replicability Issues: Laboratories may produce varying results for identical products due to differences in equipment, methodology, or sample preparation. This lack of standardization complicates regulatory compliance.

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
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Time Frame: Due to FFT, products may not make it out the door before they need to be submitted for 30 and 60 day stability testing.

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- Each lab tested lab tested their individual samples twice

RESULTS: Results confirmed substantial variability in cannabis testing:

- **Total THC Analysis**:
  - Lab 1: 11% range
  - Lab 2: 16% range
  - Duplicate results showed inconsistent outcomes, even for identical samples.
- **Total Yeast and Mold Analysis**:
  - Lab 1: 1,400–1,300,000 cfu/g
  - Lab 2: 1,100–471,000 cfu/g
  - Variability between replicates ranged up to several hundredfold.

DISCUSSION: These findings align with academic research documenting cannabis's inherent heterogeneity. Connecticut mandates batch homogenization before testing—an unfeasible standard given cannabis's natural heterogeneity. Additionally, the natural variability indicates that no single lab test is a cohesive representation of the sample.

CONCLUSION: Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting the recommendations in the above proposal, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.

Comment ID: 29
First Name: Christina
Last Name: Capitan
Commenter Email: Cannawarriors.ct@Gmail.com
Comment Input Method: Portal
Commenter Association: CT CannaWarriors
Commenter Title: Co-Founder/Cannabis Community Advocate
Posted Date: 01/10/25 04:39:06 PM
Comment:
Name: Capitan , Christina Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 To Whom It May Concern, We would like to take this opportunity to place on public record the strong disapproval of not only the recent regulation change proposal for the Connecticut Department of Consumer Protection?s medical and adult use cannabis programs, but our disapproval for the agency as a whole. We have no confidence in the department?s ability to further regulate cannabis effectively. The Department?s negligence, particularly regarding the allowance of up to 1 million parts of mold in medical cannabis for nearly a year during the COVID-19 pandemic, raises serious concerns about safety and oversight. This significant lapse in regulation jeopardizes consumer health and undermines trust in the Department's commitment to public safety. Furthermore, appointing a former drug enforcement agent and prosecutor to lead the cannabis regulatory agency is troubling. It demonstrates a lack of understanding and sensitivity toward the evolving landscape of cannabis regulation. This approach fosters skepticism about the department's intentions and ability to manage a program that should prioritize patient care and responsible use. We urge a reassessment of leadership and oversight protocols to restore public trust in the cannabis regulatory framework. Sincerely, Christina E Capitan CT CannaWarriors CannaWarriors.ct@gmail.com

Comment ID: 30
First Name: Brian
Last Name: Essenter
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Comment Input Method: Portal
Commenter Association:
Commenter Title: COO
Posted Date: 01/10/25 04:49:04 PM
Attachments:
Comment Regarding Proposed Cannabis Regulations .pdf
Comment:
Name: Essenter, Brian Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 Please see attached file for comments.

Comment Regarding Proposed Cannabis Regulations AU and MM

PRIORITY FOR THE FEEDBACK INCLUDED IN THIS DOCUMENT

1. **Considerations for the Re-evaluation of Laboratory Testing Regulations**
    a. Inherent Heterogenity of Cannabis
    b. Final Form Testing (FFT)
    c. Stability Testing
    d. Chromium Testing
    e. Out-of-Specification (OOS) Policy
    f. Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A)
2. **Extension of P&P Timeline or Expanded Regulation Flexibilities Response to Industry Capabilities**
3. **Comprehensive Summary of Recommendations**

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1. CONSIDERATIONS FOR THE RE-EVALUATION OF LABORATORY TESTING REGULATIONS

Our concerns are based on feedback from the industry, a literature review, and a recent study completed in partnership with a producer and the labs. From our perspective, it is clear that the current testing regulations are a hindrance on accuracy, price, and efficacy.

a. INHERENT HETEROGENITY OF CANNABIS

Regulations Proposed by DCP:

Homogenized Batch Preparation

Section 21a-421j-29(e):
Prior to a cannabis testing laboratory collecting samples for certificate of analysis or stability testing, a cannabis establishment shall:

- Prepare each cannabis batch in its **homogenized, final form**.
- Conduct a visual inspection for foreign matter.
- Ensure consistency and integrity between the batch and the samples taken for testingogenous Batch Sampling**

Section 21a-421j-29(g):
To ensure reliable testing, random samples taken from a cannabis batch must be representative of the **homogeneous batch**. Representative sampling requirements include at least four-tenths of one percent of the batch or specific weights or unit quantities for raw cannabis or cannabis products .

Hod Shelf-Stability Requirements Section 21a-421j-25(a):
Cannabis intended for sale must be **homogeneous** and shelf-stable for a minimum of 60 days after opening without refrigeration. This ensures consistency in cannabinoid and terpenoid concentration within the product.

Definitions of the regs

(8) "Batch" means (1) a specifically identified quantity of cannabis trim and cannabis flower, uniform in character and quality, from the same seed stock or cuttings taken from cannabis plants of the same genotype and phenotype, that has undergone the same propagation and cultivation processes, and harvested within a seventy-two hour period, in the same environment, and cured under the same conditions, or (2) a distinct group of cannabis product, uniform in character and quality, that has been produced in the same environment, under the same conditions, and from the same processes, equipment, and ingredients during the same cycle;

(41) "Homogenous" or "Homogenized" means uniform in cannabinoid and terpenoid concentration;

(68) "Sample" means a portion or part of a batch, the characteristics of which represent, as accurately as possible, the entire batch, allowing for the cannabis testing laboratory testing results of the sample to be generally applied to the entire batch;

Discussion:

Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A) notes a statistically significant variance in microbial and potency results in three methods of evaluation:

- Within the the same cannabis batch
- When retesting the same sample
- When the same batch cannabis is tested in different labs
- Batch homogenization before testing— is an unfeasible standard given cannabis's natural heterogeneity.

Plant Heterogeneity: Cannabis is a complex botanical product with natural variability in composition. Heavy metals, including chromium, may accumulate differently across parts of the plant (e.g., roots, stems, and flowers), making representative sampling difficult.

Inherent Heterogeneity: Cannabis is a natural product with significant variability in cannabinoid and terpene concentrations across different parts of the plant. Even within a single batch, slight differences in moisture content, particle size, or composition can lead to inconsistent test results.

Formulation Variability: Final products like edibles, tinctures, and topicals are often complex formulations that require homogenization for accurate testing. Achieving and verifying this homogenization is difficult, especially for products like infused flower or layered edibles.

Heterogeneity Recognition of Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

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b. FINAL FORM TESTING (FFT)

Regulations Proposed by DCP:

Preparation in Final Form: Section 21a-421j-29(e): Before a cannabis testing laboratory collects samples for a certificate of analysis or stability testing:

- The cannabis batch must be prepared in its homogenized, final form.
- A visual inspection for foreign matter is required.
- The entire batch must be placed in final packaging to ensure consistency and integrity between the batch and the sampled product.

Batch Size and Testing: Section 21a-421j-29(g): Representative random samples must be taken from batches prepared in their final form. Sample quantities depend on the batch size to ensure accurate representation and testing.

Isolation of Final Form Batches During Testing: Section 21a-421j-29(h): While a batch is being tested for a certificate of analysis, it must be withheld from use, stored securely, and only released upon satisfactory test results.

Packaging and Labeling: Section 21a-421j-30(f): Cannabis or cannabis products may only be labeled with a product name if their composition matches the registered final form and the cannabinoid/terpenoid profiles fall within 90–110% of the registered values.

Storage and Handling Requirements For All Found in The Regs: Section 21a-421j- 24. Minimum requirements for the storage and handling of cannabis by a producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter. (a) A producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter shall: (1) Maintain all production, manufacturing, handling and storage areas with adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions for cannabis that meet the standards set forth under 21 CFR Part 211 Subpart C except as otherwise expressly permitted by the commissioner, and except that outdoor grow handling and storage areas need only meet the requirements of these policies and procedures;

- Section 21a-421j-25. Cannabis Manufacturing Restrictions. (a) Except as otherwise provided in section 21a-421j-28 of these Policies and Procedures, cannabis permitted for sale to a consumer, qualifying patient or caregiver shall meet the following requirements, and any cannabis not in compliance with this section shall be deemed adulterated:
- (1) Cannabis shall be homogenous and shelf-stable for a minimum of sixty days after opening without refrigeration. (2) Cannabis products shall only be produced and manufactured in compliance with 21 CFR Part 211 Subpart B, (A) using ingredients and components permitted by the U.S. Food and Drug Administration for the specified use in food or food manufacturing pursuant to the Substances Added to Food inventory, if edible, (B) with equipment that meets the standards set forth under 21 CFR Part 211 Subpart D, and (C) in facilities that meet the standards set forth under 21 CFR Part 211 Subpart C.
- (D) Documenting the chain of custody of all cannabis, in compliance with 21 CFR Part 211 Subpart J, which documentation shall include, but not be limited to, the name of each employee that conducts an activity required to be recorded.
- Connecticut Food, Drug and Cosmetic Act, sections 21a91 to 21a-120, inclusive, and sections 21a-151 to 21a-159, inclusive, of the Connecticut General Statutes, regarding bakeries and food manufacturing establishments.
- Section 21a-421j-29. Cannabis Testing Laboratory Processes and Testing. (g) [On or before] Prior to January 1, 2025, the number of random samples, sufficient to ensure a representative sampling, taken from a cannabis batch [must] shall be representative of the

homogenous batch to ensure reliable testing. On or after January 1, 2025, the quantity and number of cannabis samples taken for certificate of analysis testing pursuant to subsection (i) of this section shall be taken at random, sufficient to ensure representative sampling of the corresponding batch. Representative samples shall consist of at least four tenths of one percent of the batch, but in no circumstance less than twenty grams for raw cannabis or, for cannabis products, the number of units required in accordance with the following table:

Discussion: In 2018, under the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), California implemented Final Form Testing but abandoned it in 2020 with Assembly Bill 1470 due to inefficiency and high costs to the detriment of the industry with no added value to consumers or regulators. Assembly Bill 1470 redefined “final form” to mean “the unpackaged product as it will be consumed,” allowing for batch testing of unpackaged products. This shift reduced waste, improved efficiency, and highlighted the failure of final form testing. Packaging can be tested as part of process validation, including the evaluation and qualification of container-closure systems and stability determinations for finished product batches.

- "...In the pharma [industry], you don't test the product in it's final packaging.... but you can be delivered that final form in bulk to test the product...get the COA...release it...then package it."
- "Every sample sent to a lab has to be opened by a lab technician. Multiply this mind-numbing time-losing activity by thousands of samples."
- **Testing in Final Form vs Final Packaging:** https://youtu.be/oNq-bL6Vimk?si=kCCl4xgrJNiY75t1

While FFT intends to that cannabis products meet safety and quality standards, its implementation presents significant challenges, particularly for high-variability products and small businesses. Addressing these issues requires regulatory flexibility, improved testing methodologies, and consideration of alternatives like IBT to balance safety, cost, and efficiency.Final Form Testing (FFT) in cannabis presents several challenges related to practicality, consistency, and cost. These issues stem from the inherent variability in cannabis products, the complexities of testing processes, and logistical constraints. Below is an overview of the primary challenges:

- **Conflicting Recovery Standards**: The state’s recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures.
- **Final Form Testing Intent** is to test the product at the point of consumption. Notably to identify if the package is creating contamination. Packaging can be tested independently for potential contaminates that could bio accumulate.

Increased Opportunity For Error:

- **21 CFR Part 211 Subparts B, C, and D** as referenced the DCPs Proposed Regulations speak repeatedly to the mitigating the opportunity for mixups, and keeping products labeled, and making sure that facilities are structured to accommodate these demands of operation. These newly referenced regulations speak to mix-ups and concerns that they would use to prep in a pharmaceutical facility
- **FFT testing requires operators** to hold on 6-10 weeks of unlabeled product, in secure storage space, that the facilities were not designed to manages. This inherently required operators to act in direct opposition to the **21 CFR Part 211** guidelines.

Costly Process: Testing every individual product in its packaged, "final form" state can significantly increase costs for producers, as each variant and SKU requires separate testing.

Delayed Time Frame For Product To Get To Market: Final form testing requires that every unique product be tested after packaging, which complicates supply chain workflows and slows down the release of products to market.

Randomized Sampling: Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.

Disproportionate Burden on Small Operators: Smaller cannabis businesses often lack the resources to manage the increased costs and operational complexity associated with FFT.

Replicability Issues: Laboratories may produce varying results for identical products due to differences in equipment, methodology, or sample preparation. This lack of standardization complicates regulatory compliance.

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

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c. STABILITY TESTING STANDARDS

Regulations Proposed by DCP:

Stability Testing in Final Packaging

- Section 21a-421j-30(b): Stability testing is mandatory for cannabis products in their final packaging, including:
    a. The first registered batch in each product category.
    b. First batch of each registered beverage, edible product, or vape oil.
    c. Stability testing intervals: 30 and 60 days.
    d. Samples must undergo cannabinoid, heavy metal, and microbial testing.
    e. The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis.

Homogeneity in Final Packaging

- Section 21a-421j-30(e): If stability test results fall outside the acceptable range (90–110%), the label must be updated to reflect the actual composition and expiration date. This ensures that the cannabis or cannabis product in final form matches its registered attribute*s.*

Discussion:

Stability Concerns: FFT often requires that cannabinoid content remains within a specific percentage of the labeled claim over time (e.g., ±10%). Due to the natural degradation of cannabinoids and terpenes during storage, many products fail stability tests despite being safe and effective.

Time Frame: Due to FFT, products may not make it out the door before they need to be submitted for 30 and 60 day stability testing.

Potency Variability with Stability Testing and Conflicting Recovery Standards: The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis. Additionally, the state's recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures."By unnecessarily reporting results to the one-hundredth percentile, some labs created an unrealistic illusion of precision that raises false expectations regarding the degree to which accuracy is possible, given the 20% variation observed."
https://www.canorml.org/business-resources-for-cannabis-brands/how-accurate-is-cannabis-potency-testing/

Packaging Interference: Packaging materials can interact with the product during testing, introducing variables that skew results (e.g., THC adhering to certain plastics).

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Replace stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

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d. CHROMIUM TESTING

Regulations Proposed by DCP:

Section 21a-421j-29(i)(3):

- Cannabis samples must be tested for heavy metals, including chromium, to ensure compliance with the following thresholds:
  - Inhalation Route: ≤ 0.6 µg/g
  - Non-Inhalation Route: ≤ 2.0 µg/g
- These limits ensure the product is safe for consumption or use according to the intended delivery metho*d.*

Discussion: Chromium is not commonly tested in cannabis products across most states. This concern is better addressed through periodic monitoring within a comprehensive Hazard Analysis and Critical Control Points (HACCP) program rather than testing individual products. Such an approach allows for proactive identification and mitigation of contamination risks in cultivation environments.

However, we recognize the unique risks posed by vaporizable cannabis products, where chromium may accumulate in heating elements or delivery systems. These scenarios may require alternative considerations, including targeted testing or material-specific evaluations, to ensure consumer safety.

Differentiation of Chromium Species: Chromium exists in multiple oxidation states, primarily trivalent (essential and less toxic) and hexavalent (highly toxic). Accurately differentiating

between these species requires advanced instrumentation like inductively coupled plasma-mass spectrometry (ICP-MS) combined with specific sample preparation techniques.

During Processing: Chromium contamination can occur from processing equipment or packaging materials, leading to higher detected levels. For example, stainless steels (the gold standard for use in facilities can falsely elevate the detectable chromium levels due Chromium oxide which resides on the surfaces.

Complex Matrices: Cannabis samples contain organic compounds, cannabinoids, and terpenes that can interfere with heavy metal analysis. Proper sample digestion and matrix removal are crucial for accurate chromium detection.

Moisture Content: Variations in cannabis moisture levels can affect the concentration calculations of heavy metals in dry weight samples, introducing potential inaccuracies.

Equipment Calibration: Differences in the calibration of ICP-MS or atomic absorption spectrometers can result in inconsistent chromium measurements.

Lack of Standardized Limits: Chromium testing guidelines and permissible limits vary widely Some states or countries may not specify limits for chromium or differentiate between its forms.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.
- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

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e. OUT-OF SPECIFICATION (OOS) POLICY

Regulations Proposed by DCP:

Failed Microbiological Testing and Retesting Requirements

- If a cannabis sample does not yield satisfactory results during microbiological testing, the cannabis establishment must follow specific procedures:
    - Enter all analysis and test results into the Cannabis Analytic Tracking System.
    - Dispose of the cannabis sample according to Section 21a-421j-3 of the Regulations of Connecticut State Agencies.
    - Comply with retesting, remediation, and disposal provisions as outlined in Section 3 of Public Act 24-76.

Discussion:

Out-of-Specification (OOS) Policy: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory error

Lack of Retesting Policies: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory errors. This can cost operators tens of thousands of dollars per batch of failed testing.

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

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2. EXTENTION OF P&P TIMEFRAME OR EXPANDED REGULATION FLEXIBILITIES RESPONSIVE TO INDUSTRY CAPABILITIES

Regulations Proposed by DCP:

Discussion: Proposed regulations do not allow for urgent changes to cannabis operations and requirements. This is of great concern as many of the first round of licensees have not opened their businesses yet. This disregards the opportunity for the Department to gather information to guide the operations of these new license types.

P&P Time Frams Recommendations: Regulatory Recommendation: Extend the policies and procedures (P&P) review process for an additional 12 months or include a provision granting the Commissioner the authority to adapt regulations at their discretion based on emerging industry information and developments.

3. COMPREHENSIVE SUMMARY OF RECOMMENDATIONS

Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting these recommendations, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.To address these issues, we propose the following recommendations

Heterogeneity Recognition Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
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APPENDIX A

A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis

INTRODUCTION: This study was conducted to better understand the variances in testing that can be seen in microbiology and potency test for cannabis flower. This study compares these factors across the batch, within the same sample, and between separate labs,

MATERIALS AND METHODS: A controlled study conducted at two labs analyzed 15 samples in duplicate, yielding 30 data points per lab, per test.

- 30 samples of Cannabis were selected from a single batch
- 2 separate labs received 15 samples of each
- Each lab tested 15 samples for THC and for 15 Micro
- Each lab tested lab tested their individual samples twice

RESULTS: Results confirmed substantial variability in cannabis testing:

- **Total THC Analysis**:
  - Lab 1: 11% range
  - Lab 2: 16% range
  - Duplicate results showed inconsistent outcomes, even for identical samples.
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Comment ID: 31
First Name: Tyler
Last Name: OHazo
Commenter Email: tyler.o@ctdutch.com
Comment Input Method: Portal
Commenter Association:
Commenter Title:
Posted Date: 01/10/25 04:54:10 PM
Attachments:
Comment Regarding Proposed Cannabis Regulations (1).pdf
Comment:
Name: OHazo, Tyler Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 Greetings - I respectfully request your consideration of the comments attached below. Thank you, Tyler O'Hazo, Dutch LLC.

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- (D) Documenting the chain of custody of all cannabis, in compliance with 21 CFR Part 211 Subpart J, which documentation shall include, but not be limited to, the name of each employee that conducts an activity required to be recorded.
- Connecticut Food, Drug and Cosmetic Act, sections 21a91 to 21a-120, inclusive, and sections 21a-151 to 21a-159, inclusive, of the Connecticut General Statutes, regarding bakeries and food manufacturing establishments.
- Section 21a-421j-29. Cannabis Testing Laboratory Processes and Testing. (g) [On or before] Prior to January 1, 2025, the number of random samples, sufficient to ensure a representative sampling, taken from a cannabis batch [must] shall be representative of the

homogenous batch to ensure reliable testing. On or after January 1, 2025, the quantity and number of cannabis samples taken for certificate of analysis testing pursuant to subsection (i) of this section shall be taken at random, sufficient to ensure representative sampling of the corresponding batch. Representative samples shall consist of at least four tenths of one percent of the batch, but in no circumstance less than twenty grams for raw cannabis or, for cannabis products, the number of units required in accordance with the following table:

Discussion: In 2018, under the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), California implemented Final Form Testing but abandoned it in 2020 with Assembly Bill 1470 due to inefficiency and high costs to the detriment of the industry with no added value to consumers or regulators. Assembly Bill 1470 redefined “final form” to mean “the unpackaged product as it will be consumed,” allowing for batch testing of unpackaged products. This shift reduced waste, improved efficiency, and highlighted the failure of final form testing. Packaging can be tested as part of process validation, including the evaluation and qualification of container-closure systems and stability determinations for finished product batches.

- "...In the pharma [industry], you don't test the product in it's final packaging.... but you can be delivered that final form in bulk to test the product...get the COA...release it...then package it."
- "Every sample sent to a lab has to be opened by a lab technician. Multiply this mind-numbing time-losing activity by thousands of samples."
- **Testing in Final Form vs Final Packaging:** https://youtu.be/oNq-bL6Vimk?si=kCCl4xgrJNiY75t1

While FFT intends to that cannabis products meet safety and quality standards, its implementation presents significant challenges, particularly for high-variability products and small businesses. Addressing these issues requires regulatory flexibility, improved testing methodologies, and consideration of alternatives like IBT to balance safety, cost, and efficiency.Final Form Testing (FFT) in cannabis presents several challenges related to practicality, consistency, and cost. These issues stem from the inherent variability in cannabis products, the complexities of testing processes, and logistical constraints. Below is an overview of the primary challenges:

- **Conflicting Recovery Standards**: The state’s recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures.
- **Final Form Testing Intent** is to test the product at the point of consumption. Notably to identify if the package is creating contamination. Packaging can be tested independently for potential contaminates that could bio accumulate.

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- **FFT testing requires operators** to hold on 6-10 weeks of unlabeled product, in secure storage space, that the facilities were not designed to manages. This inherently required operators to act in direct opposition to the **21 CFR Part 211** guidelines.

Costly Process: Testing every individual product in its packaged, "final form" state can significantly increase costs for producers, as each variant and SKU requires separate testing.

Delayed Time Frame For Product To Get To Market: Final form testing requires that every unique product be tested after packaging, which complicates supply chain workflows and slows down the release of products to market.

Randomized Sampling: Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.

Disproportionate Burden on Small Operators: Smaller cannabis businesses often lack the resources to manage the increased costs and operational complexity associated with FFT.

Replicability Issues: Laboratories may produce varying results for identical products due to differences in equipment, methodology, or sample preparation. This lack of standardization complicates regulatory compliance.

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

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c. STABILITY TESTING STANDARDS

Regulations Proposed by DCP:

Stability Testing in Final Packaging

- Section 21a-421j-30(b): Stability testing is mandatory for cannabis products in their final packaging, including:
    a. The first registered batch in each product category.
    b. First batch of each registered beverage, edible product, or vape oil.
    c. Stability testing intervals: 30 and 60 days.
    d. Samples must undergo cannabinoid, heavy metal, and microbial testing.
    e. The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis.

Homogeneity in Final Packaging

- Section 21a-421j-30(e): If stability test results fall outside the acceptable range (90–110%), the label must be updated to reflect the actual composition and expiration date. This ensures that the cannabis or cannabis product in final form matches its registered attribute*s.*

Discussion:

Stability Concerns: FFT often requires that cannabinoid content remains within a specific percentage of the labeled claim over time (e.g., ±10%). Due to the natural degradation of cannabinoids and terpenes during storage, many products fail stability tests despite being safe and effective.

Time Frame: Due to FFT, products may not make it out the door before they need to be submitted for 30 and 60 day stability testing.

Potency Variability with Stability Testing and Conflicting Recovery Standards: The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis. Additionally, the state's recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures."By unnecessarily reporting results to the one-hundredth percentile, some labs created an unrealistic illusion of precision that raises false expectations regarding the degree to which accuracy is possible, given the 20% variation observed."
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Packaging Interference: Packaging materials can interact with the product during testing, introducing variables that skew results (e.g., THC adhering to certain plastics).

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Replace stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

---

d. CHROMIUM TESTING

Regulations Proposed by DCP:

Section 21a-421j-29(i)(3):

- Cannabis samples must be tested for heavy metals, including chromium, to ensure compliance with the following thresholds:
  - Inhalation Route: ≤ 0.6 µg/g
  - Non-Inhalation Route: ≤ 2.0 µg/g
- These limits ensure the product is safe for consumption or use according to the intended delivery metho*d.*

Discussion: Chromium is not commonly tested in cannabis products across most states. This concern is better addressed through periodic monitoring within a comprehensive Hazard Analysis and Critical Control Points (HACCP) program rather than testing individual products. Such an approach allows for proactive identification and mitigation of contamination risks in cultivation environments.

However, we recognize the unique risks posed by vaporizable cannabis products, where chromium may accumulate in heating elements or delivery systems. These scenarios may require alternative considerations, including targeted testing or material-specific evaluations, to ensure consumer safety.

Differentiation of Chromium Species: Chromium exists in multiple oxidation states, primarily trivalent (essential and less toxic) and hexavalent (highly toxic). Accurately differentiating

between these species requires advanced instrumentation like inductively coupled plasma-mass spectrometry (ICP-MS) combined with specific sample preparation techniques.

During Processing: Chromium contamination can occur from processing equipment or packaging materials, leading to higher detected levels. For example, stainless steels (the gold standard for use in facilities can falsely elevate the detectable chromium levels due Chromium oxide which resides on the surfaces.

Complex Matrices: Cannabis samples contain organic compounds, cannabinoids, and terpenes that can interfere with heavy metal analysis. Proper sample digestion and matrix removal are crucial for accurate chromium detection.

Moisture Content: Variations in cannabis moisture levels can affect the concentration calculations of heavy metals in dry weight samples, introducing potential inaccuracies.

Equipment Calibration: Differences in the calibration of ICP-MS or atomic absorption spectrometers can result in inconsistent chromium measurements.

Lack of Standardized Limits: Chromium testing guidelines and permissible limits vary widely Some states or countries may not specify limits for chromium or differentiate between its forms.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.
- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

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e. OUT-OF SPECIFICATION (OOS) POLICY

Regulations Proposed by DCP:

Failed Microbiological Testing and Retesting Requirements

- If a cannabis sample does not yield satisfactory results during microbiological testing, the cannabis establishment must follow specific procedures:
    - Enter all analysis and test results into the Cannabis Analytic Tracking System.
    - Dispose of the cannabis sample according to Section 21a-421j-3 of the Regulations of Connecticut State Agencies.
    - Comply with retesting, remediation, and disposal provisions as outlined in Section 3 of Public Act 24-76.

Discussion:

Out-of-Specification (OOS) Policy: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory error

Lack of Retesting Policies: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory errors. This can cost operators tens of thousands of dollars per batch of failed testing.

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

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2. EXTENTION OF P&P TIMEFRAME OR EXPANDED REGULATION FLEXIBILITIES RESPONSIVE TO INDUSTRY CAPABILITIES

Regulations Proposed by DCP:

Discussion: Proposed regulations do not allow for urgent changes to cannabis operations and requirements. This is of great concern as many of the first round of licensees have not opened their businesses yet. This disregards the opportunity for the Department to gather information to guide the operations of these new license types.

P&P Time Frams Recommendations: Regulatory Recommendation: Extend the policies and procedures (P&P) review process for an additional 12 months or include a provision granting the Commissioner the authority to adapt regulations at their discretion based on emerging industry information and developments.

3. COMPREHENSIVE SUMMARY OF RECOMMENDATIONS

Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting these recommendations, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.To address these issues, we propose the following recommendations

Heterogeneity Recognition Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Consider stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.

- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

P&P Time Frams Recommendations: Regulatory Recommendation: Extend the policies and procedures (P&P) review process for an additional 12 months or include a provision granting the Commissioner the authority to adapt regulations at their discretion based on emerging industry information and developments.

APPENDIX A

A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis

INTRODUCTION: This study was conducted to better understand the variances in testing that can be seen in microbiology and potency test for cannabis flower. This study compares these factors across the batch, within the same sample, and between separate labs,

MATERIALS AND METHODS: A controlled study conducted at two labs analyzed 15 samples in duplicate, yielding 30 data points per lab, per test.

- 30 samples of Cannabis were selected from a single batch
- 2 separate labs received 15 samples of each
- Each lab tested 15 samples for THC and for 15 Micro
- Each lab tested lab tested their individual samples twice

RESULTS: Results confirmed substantial variability in cannabis testing:

- **Total THC Analysis**:
  - Lab 1: 11% range
  - Lab 2: 16% range
  - Duplicate results showed inconsistent outcomes, even for identical samples.
- **Total Yeast and Mold Analysis**:
  - Lab 1: 1,400–1,300,000 cfu/g
  - Lab 2: 1,100–471,000 cfu/g
  - Variability between replicates ranged up to several hundredfold.

DISCUSSION: These findings align with academic research documenting cannabis's inherent heterogeneity. Connecticut mandates batch homogenization before testing—an unfeasible standard given cannabis's natural heterogeneity. Additionally, the natural variability indicates that no single lab test is a cohesive representation of the sample.

CONCLUSION: Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting the recommendations in the above proposal, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.

Comment ID: 32
First Name: Marghie
Last Name: Giuliano
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Comment Input Method: Portal
Commenter Association: Fine Fettle
Commenter Title: Chief Compliance Officer
Posted Date: 01/10/25 04:58:26 PM
Attachments:
Comment Regarding Proposed Cannabis Regulations .pdf
Comment:
Name: Giuliano, Marghie Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 This is a safe and smart way to test product for the consumer and industry

Comment Regarding Proposed Cannabis Regulations AU and MM

PRIORITY FOR THE FEEDBACK INCLUDED IN THIS DOCUMENT

1. **Considerations for the Re-evaluation of Laboratory Testing Regulations**
    a. Inherent Heterogenity of Cannabis
    b. Final Form Testing (FFT)
    c. Stability Testing
    d. Chromium Testing
    e. Out-of-Specification (OOS) Policy
    f. Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A)
2. **Extension of P&P Timeline or Expanded Regulation Flexibilities Response to Industry Capabilities**
3. **Comprehensive Summary of Recommendations**

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1. CONSIDERATIONS FOR THE RE-EVALUATION OF LABORATORY TESTING REGULATIONS

Our concerns are based on feedback from the industry, a literature review, and a recent study completed in partnership with a producer and the labs. From our perspective, it is clear that the current testing regulations are a hindrance on accuracy, price, and efficacy.

a. INHERENT HETEROGENITY OF CANNABIS

Regulations Proposed by DCP:

Homogenized Batch Preparation

Section 21a-421j-29(e):
Prior to a cannabis testing laboratory collecting samples for certificate of analysis or stability testing, a cannabis establishment shall:

- Prepare each cannabis batch in its **homogenized, final form**.
- Conduct a visual inspection for foreign matter.
- Ensure consistency and integrity between the batch and the samples taken for testingogenous Batch Sampling**

Section 21a-421j-29(g):
To ensure reliable testing, random samples taken from a cannabis batch must be representative of the **homogeneous batch**. Representative sampling requirements include at least four-tenths of one percent of the batch or specific weights or unit quantities for raw cannabis or cannabis products .

Hod Shelf-Stability Requirements Section 21a-421j-25(a):
Cannabis intended for sale must be **homogeneous** and shelf-stable for a minimum of 60 days after opening without refrigeration. This ensures consistency in cannabinoid and terpenoid concentration within the product.

Definitions of the regs

(8) "Batch" means (1) a specifically identified quantity of cannabis trim and cannabis flower, uniform in character and quality, from the same seed stock or cuttings taken from cannabis plants of the same genotype and phenotype, that has undergone the same propagation and cultivation processes, and harvested within a seventy-two hour period, in the same environment, and cured under the same conditions, or (2) a distinct group of cannabis product, uniform in character and quality, that has been produced in the same environment, under the same conditions, and from the same processes, equipment, and ingredients during the same cycle;

(41) "Homogenous" or "Homogenized" means uniform in cannabinoid and terpenoid concentration;

(68) "Sample" means a portion or part of a batch, the characteristics of which represent, as accurately as possible, the entire batch, allowing for the cannabis testing laboratory testing results of the sample to be generally applied to the entire batch;

Discussion:

Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A) notes a statistically significant variance in microbial and potency results in three methods of evaluation:

- Within the the same cannabis batch
- When retesting the same sample
- When the same batch cannabis is tested in different labs
- Batch homogenization before testing— is an unfeasible standard given cannabis's natural heterogeneity.

Plant Heterogeneity: Cannabis is a complex botanical product with natural variability in composition. Heavy metals, including chromium, may accumulate differently across parts of the plant (e.g., roots, stems, and flowers), making representative sampling difficult.

Inherent Heterogeneity: Cannabis is a natural product with significant variability in cannabinoid and terpene concentrations across different parts of the plant. Even within a single batch, slight differences in moisture content, particle size, or composition can lead to inconsistent test results.

Formulation Variability: Final products like edibles, tinctures, and topicals are often complex formulations that require homogenization for accurate testing. Achieving and verifying this homogenization is difficult, especially for products like infused flower or layered edibles.

Heterogeneity Recognition of Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

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b. FINAL FORM TESTING (FFT)

Regulations Proposed by DCP:

Preparation in Final Form: Section 21a-421j-29(e): Before a cannabis testing laboratory collects samples for a certificate of analysis or stability testing:

- The cannabis batch must be prepared in its homogenized, final form.
- A visual inspection for foreign matter is required.
- The entire batch must be placed in final packaging to ensure consistency and integrity between the batch and the sampled product.

Batch Size and Testing: Section 21a-421j-29(g): Representative random samples must be taken from batches prepared in their final form. Sample quantities depend on the batch size to ensure accurate representation and testing.

Isolation of Final Form Batches During Testing: Section 21a-421j-29(h): While a batch is being tested for a certificate of analysis, it must be withheld from use, stored securely, and only released upon satisfactory test results.

Packaging and Labeling: Section 21a-421j-30(f): Cannabis or cannabis products may only be labeled with a product name if their composition matches the registered final form and the cannabinoid/terpenoid profiles fall within 90–110% of the registered values.

Storage and Handling Requirements For All Found in The Regs: Section 21a-421j- 24. Minimum requirements for the storage and handling of cannabis by a producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter. (a) A producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter shall: (1) Maintain all production, manufacturing, handling and storage areas with adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions for cannabis that meet the standards set forth under 21 CFR Part 211 Subpart C except as otherwise expressly permitted by the commissioner, and except that outdoor grow handling and storage areas need only meet the requirements of these policies and procedures;

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Lack of Standardized Limits: Chromium testing guidelines and permissible limits vary widely Some states or countries may not specify limits for chromium or differentiate between its forms.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.
- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

---

e. OUT-OF SPECIFICATION (OOS) POLICY

Regulations Proposed by DCP:

Failed Microbiological Testing and Retesting Requirements

- If a cannabis sample does not yield satisfactory results during microbiological testing, the cannabis establishment must follow specific procedures:
    - Enter all analysis and test results into the Cannabis Analytic Tracking System.
    - Dispose of the cannabis sample according to Section 21a-421j-3 of the Regulations of Connecticut State Agencies.
    - Comply with retesting, remediation, and disposal provisions as outlined in Section 3 of Public Act 24-76.

Discussion:

Out-of-Specification (OOS) Policy: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory error

Lack of Retesting Policies: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory errors. This can cost operators tens of thousands of dollars per batch of failed testing.

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

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2. EXTENTION OF P&P TIMEFRAME OR EXPANDED REGULATION FLEXIBILITIES RESPONSIVE TO INDUSTRY CAPABILITIES

Regulations Proposed by DCP:

Discussion: Proposed regulations do not allow for urgent changes to cannabis operations and requirements. This is of great concern as many of the first round of licensees have not opened their businesses yet. This disregards the opportunity for the Department to gather information to guide the operations of these new license types.

P&P Time Frams Recommendations: Regulatory Recommendation: Extend the policies and procedures (P&P) review process for an additional 12 months or include a provision granting the Commissioner the authority to adapt regulations at their discretion based on emerging industry information and developments.

3. COMPREHENSIVE SUMMARY OF RECOMMENDATIONS

Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting these recommendations, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.To address these issues, we propose the following recommendations

Heterogeneity Recognition Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Consider stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

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APPENDIX A

A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis

INTRODUCTION: This study was conducted to better understand the variances in testing that can be seen in microbiology and potency test for cannabis flower. This study compares these factors across the batch, within the same sample, and between separate labs,

MATERIALS AND METHODS: A controlled study conducted at two labs analyzed 15 samples in duplicate, yielding 30 data points per lab, per test.

- 30 samples of Cannabis were selected from a single batch
- 2 separate labs received 15 samples of each
- Each lab tested 15 samples for THC and for 15 Micro
- Each lab tested lab tested their individual samples twice

RESULTS: Results confirmed substantial variability in cannabis testing:

- **Total THC Analysis**:
  - Lab 1: 11% range
  - Lab 2: 16% range
  - Duplicate results showed inconsistent outcomes, even for identical samples.
- **Total Yeast and Mold Analysis**:
  - Lab 1: 1,400–1,300,000 cfu/g
  - Lab 2: 1,100–471,000 cfu/g
  - Variability between replicates ranged up to several hundredfold.

DISCUSSION: These findings align with academic research documenting cannabis's inherent heterogeneity. Connecticut mandates batch homogenization before testing—an unfeasible standard given cannabis's natural heterogeneity. Additionally, the natural variability indicates that no single lab test is a cohesive representation of the sample.

CONCLUSION: Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting the recommendations in the above proposal, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.

Comment ID: 33
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Commenter Association: Fine Fettle
Commenter Title: CEO
Posted Date: 01/10/25 04:59:20 PM
Attachments:
Comment Regarding Proposed Cannabis Regulations .pdf
Comment:
Name: Carbray, Richard Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 This is the smart and safe way to test that is good for patient AND the industry

Comment Regarding Proposed Cannabis Regulations AU and MM

PRIORITY FOR THE FEEDBACK INCLUDED IN THIS DOCUMENT

1. **Considerations for the Re-evaluation of Laboratory Testing Regulations**
    a. Inherent Heterogenity of Cannabis
    b. Final Form Testing (FFT)
    c. Stability Testing
    d. Chromium Testing
    e. Out-of-Specification (OOS) Policy
    f. Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A)
2. **Extension of P&P Timeline or Expanded Regulation Flexibilities Response to Industry Capabilities**
3. **Comprehensive Summary of Recommendations**

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1. CONSIDERATIONS FOR THE RE-EVALUATION OF LABORATORY TESTING REGULATIONS

Our concerns are based on feedback from the industry, a literature review, and a recent study completed in partnership with a producer and the labs. From our perspective, it is clear that the current testing regulations are a hindrance on accuracy, price, and efficacy.

a. INHERENT HETEROGENITY OF CANNABIS

Regulations Proposed by DCP:

Homogenized Batch Preparation

Section 21a-421j-29(e):
Prior to a cannabis testing laboratory collecting samples for certificate of analysis or stability testing, a cannabis establishment shall:

- Prepare each cannabis batch in its **homogenized, final form**.
- Conduct a visual inspection for foreign matter.
- Ensure consistency and integrity between the batch and the samples taken for testingogenous Batch Sampling**

Section 21a-421j-29(g):
To ensure reliable testing, random samples taken from a cannabis batch must be representative of the **homogeneous batch**. Representative sampling requirements include at least four-tenths of one percent of the batch or specific weights or unit quantities for raw cannabis or cannabis products .

Hod Shelf-Stability Requirements Section 21a-421j-25(a):
Cannabis intended for sale must be **homogeneous** and shelf-stable for a minimum of 60 days after opening without refrigeration. This ensures consistency in cannabinoid and terpenoid concentration within the product.

Definitions of the regs

(8) "Batch" means (1) a specifically identified quantity of cannabis trim and cannabis flower, uniform in character and quality, from the same seed stock or cuttings taken from cannabis plants of the same genotype and phenotype, that has undergone the same propagation and cultivation processes, and harvested within a seventy-two hour period, in the same environment, and cured under the same conditions, or (2) a distinct group of cannabis product, uniform in character and quality, that has been produced in the same environment, under the same conditions, and from the same processes, equipment, and ingredients during the same cycle;

(41) "Homogenous" or "Homogenized" means uniform in cannabinoid and terpenoid concentration;

(68) "Sample" means a portion or part of a batch, the characteristics of which represent, as accurately as possible, the entire batch, allowing for the cannabis testing laboratory testing results of the sample to be generally applied to the entire batch;

Discussion:

Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A) notes a statistically significant variance in microbial and potency results in three methods of evaluation:

- Within the the same cannabis batch
- When retesting the same sample
- When the same batch cannabis is tested in different labs
- Batch homogenization before testing— is an unfeasible standard given cannabis's natural heterogeneity.

Plant Heterogeneity: Cannabis is a complex botanical product with natural variability in composition. Heavy metals, including chromium, may accumulate differently across parts of the plant (e.g., roots, stems, and flowers), making representative sampling difficult.

Inherent Heterogeneity: Cannabis is a natural product with significant variability in cannabinoid and terpene concentrations across different parts of the plant. Even within a single batch, slight differences in moisture content, particle size, or composition can lead to inconsistent test results.

Formulation Variability: Final products like edibles, tinctures, and topicals are often complex formulations that require homogenization for accurate testing. Achieving and verifying this homogenization is difficult, especially for products like infused flower or layered edibles.

Heterogeneity Recognition of Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

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b. FINAL FORM TESTING (FFT)

Regulations Proposed by DCP:

Preparation in Final Form: Section 21a-421j-29(e): Before a cannabis testing laboratory collects samples for a certificate of analysis or stability testing:

- The cannabis batch must be prepared in its homogenized, final form.
- A visual inspection for foreign matter is required.
- The entire batch must be placed in final packaging to ensure consistency and integrity between the batch and the sampled product.

Batch Size and Testing: Section 21a-421j-29(g): Representative random samples must be taken from batches prepared in their final form. Sample quantities depend on the batch size to ensure accurate representation and testing.

Isolation of Final Form Batches During Testing: Section 21a-421j-29(h): While a batch is being tested for a certificate of analysis, it must be withheld from use, stored securely, and only released upon satisfactory test results.

Packaging and Labeling: Section 21a-421j-30(f): Cannabis or cannabis products may only be labeled with a product name if their composition matches the registered final form and the cannabinoid/terpenoid profiles fall within 90–110% of the registered values.

Storage and Handling Requirements For All Found in The Regs: Section 21a-421j- 24. Minimum requirements for the storage and handling of cannabis by a producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter. (a) A producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter shall: (1) Maintain all production, manufacturing, handling and storage areas with adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions for cannabis that meet the standards set forth under 21 CFR Part 211 Subpart C except as otherwise expressly permitted by the commissioner, and except that outdoor grow handling and storage areas need only meet the requirements of these policies and procedures;

- Section 21a-421j-25. Cannabis Manufacturing Restrictions. (a) Except as otherwise provided in section 21a-421j-28 of these Policies and Procedures, cannabis permitted for sale to a consumer, qualifying patient or caregiver shall meet the following requirements, and any cannabis not in compliance with this section shall be deemed adulterated:
- (1) Cannabis shall be homogenous and shelf-stable for a minimum of sixty days after opening without refrigeration. (2) Cannabis products shall only be produced and manufactured in compliance with 21 CFR Part 211 Subpart B, (A) using ingredients and components permitted by the U.S. Food and Drug Administration for the specified use in food or food manufacturing pursuant to the Substances Added to Food inventory, if edible, (B) with equipment that meets the standards set forth under 21 CFR Part 211 Subpart D, and (C) in facilities that meet the standards set forth under 21 CFR Part 211 Subpart C.
- (D) Documenting the chain of custody of all cannabis, in compliance with 21 CFR Part 211 Subpart J, which documentation shall include, but not be limited to, the name of each employee that conducts an activity required to be recorded.
- Connecticut Food, Drug and Cosmetic Act, sections 21a91 to 21a-120, inclusive, and sections 21a-151 to 21a-159, inclusive, of the Connecticut General Statutes, regarding bakeries and food manufacturing establishments.
- Section 21a-421j-29. Cannabis Testing Laboratory Processes and Testing. (g) [On or before] Prior to January 1, 2025, the number of random samples, sufficient to ensure a representative sampling, taken from a cannabis batch [must] shall be representative of the

homogenous batch to ensure reliable testing. On or after January 1, 2025, the quantity and number of cannabis samples taken for certificate of analysis testing pursuant to subsection (i) of this section shall be taken at random, sufficient to ensure representative sampling of the corresponding batch. Representative samples shall consist of at least four tenths of one percent of the batch, but in no circumstance less than twenty grams for raw cannabis or, for cannabis products, the number of units required in accordance with the following table:

Discussion: In 2018, under the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), California implemented Final Form Testing but abandoned it in 2020 with Assembly Bill 1470 due to inefficiency and high costs to the detriment of the industry with no added value to consumers or regulators. Assembly Bill 1470 redefined “final form” to mean “the unpackaged product as it will be consumed,” allowing for batch testing of unpackaged products. This shift reduced waste, improved efficiency, and highlighted the failure of final form testing. Packaging can be tested as part of process validation, including the evaluation and qualification of container-closure systems and stability determinations for finished product batches.

- "...In the pharma [industry], you don't test the product in it's final packaging.... but you can be delivered that final form in bulk to test the product...get the COA...release it...then package it."
- "Every sample sent to a lab has to be opened by a lab technician. Multiply this mind-numbing time-losing activity by thousands of samples."
- **Testing in Final Form vs Final Packaging:** https://youtu.be/oNq-bL6Vimk?si=kCCl4xgrJNiY75t1

While FFT intends to that cannabis products meet safety and quality standards, its implementation presents significant challenges, particularly for high-variability products and small businesses. Addressing these issues requires regulatory flexibility, improved testing methodologies, and consideration of alternatives like IBT to balance safety, cost, and efficiency.Final Form Testing (FFT) in cannabis presents several challenges related to practicality, consistency, and cost. These issues stem from the inherent variability in cannabis products, the complexities of testing processes, and logistical constraints. Below is an overview of the primary challenges:

- **Conflicting Recovery Standards**: The state’s recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures.
- **Final Form Testing Intent** is to test the product at the point of consumption. Notably to identify if the package is creating contamination. Packaging can be tested independently for potential contaminates that could bio accumulate.

Increased Opportunity For Error:

- **21 CFR Part 211 Subparts B, C, and D** as referenced the DCPs Proposed Regulations speak repeatedly to the mitigating the opportunity for mixups, and keeping products labeled, and making sure that facilities are structured to accommodate these demands of operation. These newly referenced regulations speak to mix-ups and concerns that they would use to prep in a pharmaceutical facility
- **FFT testing requires operators** to hold on 6-10 weeks of unlabeled product, in secure storage space, that the facilities were not designed to manages. This inherently required operators to act in direct opposition to the **21 CFR Part 211** guidelines.

Costly Process: Testing every individual product in its packaged, "final form" state can significantly increase costs for producers, as each variant and SKU requires separate testing.

Delayed Time Frame For Product To Get To Market: Final form testing requires that every unique product be tested after packaging, which complicates supply chain workflows and slows down the release of products to market.

Randomized Sampling: Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.

Disproportionate Burden on Small Operators: Smaller cannabis businesses often lack the resources to manage the increased costs and operational complexity associated with FFT.

Replicability Issues: Laboratories may produce varying results for identical products due to differences in equipment, methodology, or sample preparation. This lack of standardization complicates regulatory compliance.

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

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c. STABILITY TESTING STANDARDS

Regulations Proposed by DCP:

Stability Testing in Final Packaging

- Section 21a-421j-30(b): Stability testing is mandatory for cannabis products in their final packaging, including:
    a. The first registered batch in each product category.
    b. First batch of each registered beverage, edible product, or vape oil.
    c. Stability testing intervals: 30 and 60 days.
    d. Samples must undergo cannabinoid, heavy metal, and microbial testing.
    e. The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis.

Homogeneity in Final Packaging

- Section 21a-421j-30(e): If stability test results fall outside the acceptable range (90–110%), the label must be updated to reflect the actual composition and expiration date. This ensures that the cannabis or cannabis product in final form matches its registered attribute*s.*

Discussion:

Stability Concerns: FFT often requires that cannabinoid content remains within a specific percentage of the labeled claim over time (e.g., ±10%). Due to the natural degradation of cannabinoids and terpenes during storage, many products fail stability tests despite being safe and effective.

Time Frame: Due to FFT, products may not make it out the door before they need to be submitted for 30 and 60 day stability testing.

Potency Variability with Stability Testing and Conflicting Recovery Standards: The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis. Additionally, the state's recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures."By unnecessarily reporting results to the one-hundredth percentile, some labs created an unrealistic illusion of precision that raises false expectations regarding the degree to which accuracy is possible, given the 20% variation observed."
https://www.canorml.org/business-resources-for-cannabis-brands/how-accurate-is-cannabis-potency-testing/

Packaging Interference: Packaging materials can interact with the product during testing, introducing variables that skew results (e.g., THC adhering to certain plastics).

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Replace stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

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d. CHROMIUM TESTING

Regulations Proposed by DCP:

Section 21a-421j-29(i)(3):

- Cannabis samples must be tested for heavy metals, including chromium, to ensure compliance with the following thresholds:
  - Inhalation Route: ≤ 0.6 µg/g
  - Non-Inhalation Route: ≤ 2.0 µg/g
- These limits ensure the product is safe for consumption or use according to the intended delivery metho*d.*

Discussion: Chromium is not commonly tested in cannabis products across most states. This concern is better addressed through periodic monitoring within a comprehensive Hazard Analysis and Critical Control Points (HACCP) program rather than testing individual products. Such an approach allows for proactive identification and mitigation of contamination risks in cultivation environments.

However, we recognize the unique risks posed by vaporizable cannabis products, where chromium may accumulate in heating elements or delivery systems. These scenarios may require alternative considerations, including targeted testing or material-specific evaluations, to ensure consumer safety.

Differentiation of Chromium Species: Chromium exists in multiple oxidation states, primarily trivalent (essential and less toxic) and hexavalent (highly toxic). Accurately differentiating

between these species requires advanced instrumentation like inductively coupled plasma-mass spectrometry (ICP-MS) combined with specific sample preparation techniques.

During Processing: Chromium contamination can occur from processing equipment or packaging materials, leading to higher detected levels. For example, stainless steels (the gold standard for use in facilities can falsely elevate the detectable chromium levels due Chromium oxide which resides on the surfaces.

Complex Matrices: Cannabis samples contain organic compounds, cannabinoids, and terpenes that can interfere with heavy metal analysis. Proper sample digestion and matrix removal are crucial for accurate chromium detection.

Moisture Content: Variations in cannabis moisture levels can affect the concentration calculations of heavy metals in dry weight samples, introducing potential inaccuracies.

Equipment Calibration: Differences in the calibration of ICP-MS or atomic absorption spectrometers can result in inconsistent chromium measurements.

Lack of Standardized Limits: Chromium testing guidelines and permissible limits vary widely Some states or countries may not specify limits for chromium or differentiate between its forms.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.
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Posted Date: 01/10/25 04:59:39 PM
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Comment Regarding Proposed Cannabis Regulations .pdf
Comment:
Name: Daddario, James Submission Date: 1/10/2025 Agency: Department of Consumer Protection Subject: Regulation of Adult Use Cannabis Tracking Number: PR2024-053 This is my recommendation and feedback for the proposed 2025 cannabis regulations

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- Batch homogenization before testing— is an unfeasible standard given cannabis's natural heterogeneity.

Plant Heterogeneity: Cannabis is a complex botanical product with natural variability in composition. Heavy metals, including chromium, may accumulate differently across parts of the plant (e.g., roots, stems, and flowers), making representative sampling difficult.

Inherent Heterogeneity: Cannabis is a natural product with significant variability in cannabinoid and terpene concentrations across different parts of the plant. Even within a single batch, slight differences in moisture content, particle size, or composition can lead to inconsistent test results.

Formulation Variability: Final products like edibles, tinctures, and topicals are often complex formulations that require homogenization for accurate testing. Achieving and verifying this homogenization is difficult, especially for products like infused flower or layered edibles.

Heterogeneity Recognition of Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

---

b. FINAL FORM TESTING (FFT)

Regulations Proposed by DCP:

Preparation in Final Form: Section 21a-421j-29(e): Before a cannabis testing laboratory collects samples for a certificate of analysis or stability testing:

- The cannabis batch must be prepared in its homogenized, final form.
- A visual inspection for foreign matter is required.
- The entire batch must be placed in final packaging to ensure consistency and integrity between the batch and the sampled product.

Batch Size and Testing: Section 21a-421j-29(g): Representative random samples must be taken from batches prepared in their final form. Sample quantities depend on the batch size to ensure accurate representation and testing.

Isolation of Final Form Batches During Testing: Section 21a-421j-29(h): While a batch is being tested for a certificate of analysis, it must be withheld from use, stored securely, and only released upon satisfactory test results.

Packaging and Labeling: Section 21a-421j-30(f): Cannabis or cannabis products may only be labeled with a product name if their composition matches the registered final form and the cannabinoid/terpenoid profiles fall within 90–110% of the registered values.

Storage and Handling Requirements For All Found in The Regs: Section 21a-421j- 24. Minimum requirements for the storage and handling of cannabis by a producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter. (a) A producer, cultivator, micro-cultivator, food and beverage manufacturer, product manufacturer, product packager, delivery service, and transporter shall: (1) Maintain all production, manufacturing, handling and storage areas with adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions for cannabis that meet the standards set forth under 21 CFR Part 211 Subpart C except as otherwise expressly permitted by the commissioner, and except that outdoor grow handling and storage areas need only meet the requirements of these policies and procedures;

- Section 21a-421j-25. Cannabis Manufacturing Restrictions. (a) Except as otherwise provided in section 21a-421j-28 of these Policies and Procedures, cannabis permitted for sale to a consumer, qualifying patient or caregiver shall meet the following requirements, and any cannabis not in compliance with this section shall be deemed adulterated:
- (1) Cannabis shall be homogenous and shelf-stable for a minimum of sixty days after opening without refrigeration. (2) Cannabis products shall only be produced and manufactured in compliance with 21 CFR Part 211 Subpart B, (A) using ingredients and components permitted by the U.S. Food and Drug Administration for the specified use in food or food manufacturing pursuant to the Substances Added to Food inventory, if edible, (B) with equipment that meets the standards set forth under 21 CFR Part 211 Subpart D, and (C) in facilities that meet the standards set forth under 21 CFR Part 211 Subpart C.
- (D) Documenting the chain of custody of all cannabis, in compliance with 21 CFR Part 211 Subpart J, which documentation shall include, but not be limited to, the name of each employee that conducts an activity required to be recorded.
- Connecticut Food, Drug and Cosmetic Act, sections 21a91 to 21a-120, inclusive, and sections 21a-151 to 21a-159, inclusive, of the Connecticut General Statutes, regarding bakeries and food manufacturing establishments.
- Section 21a-421j-29. Cannabis Testing Laboratory Processes and Testing. (g) [On or before] Prior to January 1, 2025, the number of random samples, sufficient to ensure a representative sampling, taken from a cannabis batch [must] shall be representative of the

homogenous batch to ensure reliable testing. On or after January 1, 2025, the quantity and number of cannabis samples taken for certificate of analysis testing pursuant to subsection (i) of this section shall be taken at random, sufficient to ensure representative sampling of the corresponding batch. Representative samples shall consist of at least four tenths of one percent of the batch, but in no circumstance less than twenty grams for raw cannabis or, for cannabis products, the number of units required in accordance with the following table:

Discussion: In 2018, under the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), California implemented Final Form Testing but abandoned it in 2020 with Assembly Bill 1470 due to inefficiency and high costs to the detriment of the industry with no added value to consumers or regulators. Assembly Bill 1470 redefined “final form” to mean “the unpackaged product as it will be consumed,” allowing for batch testing of unpackaged products. This shift reduced waste, improved efficiency, and highlighted the failure of final form testing. Packaging can be tested as part of process validation, including the evaluation and qualification of container-closure systems and stability determinations for finished product batches.

- "...In the pharma [industry], you don't test the product in it's final packaging.... but you can be delivered that final form in bulk to test the product...get the COA...release it...then package it."
- "Every sample sent to a lab has to be opened by a lab technician. Multiply this mind-numbing time-losing activity by thousands of samples."
- **Testing in Final Form vs Final Packaging:** https://youtu.be/oNq-bL6Vimk?si=kCCl4xgrJNiY75t1

While FFT intends to that cannabis products meet safety and quality standards, its implementation presents significant challenges, particularly for high-variability products and small businesses. Addressing these issues requires regulatory flexibility, improved testing methodologies, and consideration of alternatives like IBT to balance safety, cost, and efficiency.Final Form Testing (FFT) in cannabis presents several challenges related to practicality, consistency, and cost. These issues stem from the inherent variability in cannabis products, the complexities of testing processes, and logistical constraints. Below is an overview of the primary challenges:

- **Conflicting Recovery Standards**: The state’s recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures.
- **Final Form Testing Intent** is to test the product at the point of consumption. Notably to identify if the package is creating contamination. Packaging can be tested independently for potential contaminates that could bio accumulate.

Increased Opportunity For Error:

- **21 CFR Part 211 Subparts B, C, and D** as referenced the DCPs Proposed Regulations speak repeatedly to the mitigating the opportunity for mixups, and keeping products labeled, and making sure that facilities are structured to accommodate these demands of operation. These newly referenced regulations speak to mix-ups and concerns that they would use to prep in a pharmaceutical facility
- **FFT testing requires operators** to hold on 6-10 weeks of unlabeled product, in secure storage space, that the facilities were not designed to manages. This inherently required operators to act in direct opposition to the **21 CFR Part 211** guidelines.

Costly Process: Testing every individual product in its packaged, "final form" state can significantly increase costs for producers, as each variant and SKU requires separate testing.

Delayed Time Frame For Product To Get To Market: Final form testing requires that every unique product be tested after packaging, which complicates supply chain workflows and slows down the release of products to market.

Randomized Sampling: Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.

Disproportionate Burden on Small Operators: Smaller cannabis businesses often lack the resources to manage the increased costs and operational complexity associated with FFT.

Replicability Issues: Laboratories may produce varying results for identical products due to differences in equipment, methodology, or sample preparation. This lack of standardization complicates regulatory compliance.

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

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c. STABILITY TESTING STANDARDS

Regulations Proposed by DCP:

Stability Testing in Final Packaging

- Section 21a-421j-30(b): Stability testing is mandatory for cannabis products in their final packaging, including:
    a. The first registered batch in each product category.
    b. First batch of each registered beverage, edible product, or vape oil.
    c. Stability testing intervals: 30 and 60 days.
    d. Samples must undergo cannabinoid, heavy metal, and microbial testing.
    e. The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis.

Homogeneity in Final Packaging

- Section 21a-421j-30(e): If stability test results fall outside the acceptable range (90–110%), the label must be updated to reflect the actual composition and expiration date. This ensures that the cannabis or cannabis product in final form matches its registered attribute*s.*

Discussion:

Stability Concerns: FFT often requires that cannabinoid content remains within a specific percentage of the labeled claim over time (e.g., ±10%). Due to the natural degradation of cannabinoids and terpenes during storage, many products fail stability tests despite being safe and effective.

Time Frame: Due to FFT, products may not make it out the door before they need to be submitted for 30 and 60 day stability testing.

Potency Variability with Stability Testing and Conflicting Recovery Standards: The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis. Additionally, the state's recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures."By unnecessarily reporting results to the one-hundredth percentile, some labs created an unrealistic illusion of precision that raises false expectations regarding the degree to which accuracy is possible, given the 20% variation observed."
https://www.canorml.org/business-resources-for-cannabis-brands/how-accurate-is-cannabis-potency-testing/

Packaging Interference: Packaging materials can interact with the product during testing, introducing variables that skew results (e.g., THC adhering to certain plastics).

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Replace stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

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d. CHROMIUM TESTING

Regulations Proposed by DCP:

Section 21a-421j-29(i)(3):

- Cannabis samples must be tested for heavy metals, including chromium, to ensure compliance with the following thresholds:
  - Inhalation Route: ≤ 0.6 µg/g
  - Non-Inhalation Route: ≤ 2.0 µg/g
- These limits ensure the product is safe for consumption or use according to the intended delivery metho*d.*

Discussion: Chromium is not commonly tested in cannabis products across most states. This concern is better addressed through periodic monitoring within a comprehensive Hazard Analysis and Critical Control Points (HACCP) program rather than testing individual products. Such an approach allows for proactive identification and mitigation of contamination risks in cultivation environments.

However, we recognize the unique risks posed by vaporizable cannabis products, where chromium may accumulate in heating elements or delivery systems. These scenarios may require alternative considerations, including targeted testing or material-specific evaluations, to ensure consumer safety.

Differentiation of Chromium Species: Chromium exists in multiple oxidation states, primarily trivalent (essential and less toxic) and hexavalent (highly toxic). Accurately differentiating

between these species requires advanced instrumentation like inductively coupled plasma-mass spectrometry (ICP-MS) combined with specific sample preparation techniques.

During Processing: Chromium contamination can occur from processing equipment or packaging materials, leading to higher detected levels. For example, stainless steels (the gold standard for use in facilities can falsely elevate the detectable chromium levels due Chromium oxide which resides on the surfaces.

Complex Matrices: Cannabis samples contain organic compounds, cannabinoids, and terpenes that can interfere with heavy metal analysis. Proper sample digestion and matrix removal are crucial for accurate chromium detection.

Moisture Content: Variations in cannabis moisture levels can affect the concentration calculations of heavy metals in dry weight samples, introducing potential inaccuracies.

Equipment Calibration: Differences in the calibration of ICP-MS or atomic absorption spectrometers can result in inconsistent chromium measurements.

Lack of Standardized Limits: Chromium testing guidelines and permissible limits vary widely Some states or countries may not specify limits for chromium or differentiate between its forms.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.
- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

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e. OUT-OF SPECIFICATION (OOS) POLICY

Regulations Proposed by DCP:

Failed Microbiological Testing and Retesting Requirements

- If a cannabis sample does not yield satisfactory results during microbiological testing, the cannabis establishment must follow specific procedures:
    - Enter all analysis and test results into the Cannabis Analytic Tracking System.
    - Dispose of the cannabis sample according to Section 21a-421j-3 of the Regulations of Connecticut State Agencies.
    - Comply with retesting, remediation, and disposal provisions as outlined in Section 3 of Public Act 24-76.

Discussion:

Out-of-Specification (OOS) Policy: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory error

Lack of Retesting Policies: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory errors. This can cost operators tens of thousands of dollars per batch of failed testing.

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

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2. EXTENTION OF P&P TIMEFRAME OR EXPANDED REGULATION FLEXIBILITIES RESPONSIVE TO INDUSTRY CAPABILITIES

Regulations Proposed by DCP:

Discussion: Proposed regulations do not allow for urgent changes to cannabis operations and requirements. This is of great concern as many of the first round of licensees have not opened their businesses yet. This disregards the opportunity for the Department to gather information to guide the operations of these new license types.

P&P Time Frams Recommendations: Regulatory Recommendation: Extend the policies and procedures (P&P) review process for an additional 12 months or include a provision granting the Commissioner the authority to adapt regulations at their discretion based on emerging industry information and developments.

3. COMPREHENSIVE SUMMARY OF RECOMMENDATIONS

Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting these recommendations, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.To address these issues, we propose the following recommendations

Heterogeneity Recognition Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Consider stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.

- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

P&P Time Frams Recommendations: Regulatory Recommendation: Extend the policies and procedures (P&P) review process for an additional 12 months or include a provision granting the Commissioner the authority to adapt regulations at their discretion based on emerging industry information and developments.

APPENDIX A

A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis

INTRODUCTION: This study was conducted to better understand the variances in testing that can be seen in microbiology and potency test for cannabis flower. This study compares these factors across the batch, within the same sample, and between separate labs,

MATERIALS AND METHODS: A controlled study conducted at two labs analyzed 15 samples in duplicate, yielding 30 data points per lab, per test.

- 30 samples of Cannabis were selected from a single batch
- 2 separate labs received 15 samples of each
- Each lab tested 15 samples for THC and for 15 Micro
- Each lab tested lab tested their individual samples twice

RESULTS: Results confirmed substantial variability in cannabis testing:

- **Total THC Analysis**:
  - Lab 1: 11% range
  - Lab 2: 16% range
  - Duplicate results showed inconsistent outcomes, even for identical samples.
- **Total Yeast and Mold Analysis**:
  - Lab 1: 1,400–1,300,000 cfu/g
  - Lab 2: 1,100–471,000 cfu/g
  - Variability between replicates ranged up to several hundredfold.

DISCUSSION: These findings align with academic research documenting cannabis's inherent heterogeneity. Connecticut mandates batch homogenization before testing—an unfeasible standard given cannabis's natural heterogeneity. Additionally, the natural variability indicates that no single lab test is a cohesive representation of the sample.

CONCLUSION: Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting the recommendations in the above proposal, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.

Padula, Jerry

From: Chris Weldon <cweldon@staminacapitalllc.com>
Sent: Friday, January 10, 2025 5:13 PM
To: Padula, Jerry
Subject: Cat Rock Holistics (ACPM.0000550) at 436 Slater Rd in New Britain
Attachments: Comment Regarding Proposed Cannabis Regulations .pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Jerry,

We are licenses for Product Manufacturing. Cat Rock Holistics (ACPM.0000550) at 436 Slater Rd in New Britain.

I have been trying to submit this filing through the site for the past 30 minutes. Can you please take the above comments as our submission?

Thank you and have a wonderful evening.

Christopher Weldon
Portfolio Manager
Stamina Capital
cweldon@staminacapitalllc.com
917.362.7296

Comment Regarding Proposed Cannabis Regulations AU and MM

PRIORITY FOR THE FEEDBACK INCLUDED IN THIS DOCUMENT

1. **Considerations for the Re-evaluation of Laboratory Testing Regulations**
    a. Inherent Heterogenity of Cannabis
    b. Final Form Testing (FFT)
    c. Stability Testing
    d. Chromium Testing
    e. Out-of-Specification (OOS) Policy
    f. Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A)
2. **Extension of P&P Timeline or Expanded Regulation Flexibilities Response to Industry Capabilities**
3. **Comprehensive Summary of Recommendations**

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1. CONSIDERATIONS FOR THE RE-EVALUATION OF LABORATORY TESTING REGULATIONS

Our concerns are based on feedback from the industry, a literature review, and a recent study completed in partnership with a producer and the labs. From our perspective, it is clear that the current testing regulations are a hindrance on accuracy, price, and efficacy.

a. INHERENT HETEROGENITY OF CANNABIS

Regulations Proposed by DCP:

Homogenized Batch Preparation

Section 21a-421j-29(e):
Prior to a cannabis testing laboratory collecting samples for certificate of analysis or stability testing, a cannabis establishment shall:

- Prepare each cannabis batch in its **homogenized, final form**.
- Conduct a visual inspection for foreign matter.
- Ensure consistency and integrity between the batch and the samples taken for testingogenous Batch Sampling**

Section 21a-421j-29(g):
To ensure reliable testing, random samples taken from a cannabis batch must be representative of the **homogeneous batch**. Representative sampling requirements include at least four-tenths of one percent of the batch or specific weights or unit quantities for raw cannabis or cannabis products .

Hod Shelf-Stability Requirements Section 21a-421j-25(a):
Cannabis intended for sale must be **homogeneous** and shelf-stable for a minimum of 60 days after opening without refrigeration. This ensures consistency in cannabinoid and terpenoid concentration within the product.

Definitions of the regs

(8) "Batch" means (1) a specifically identified quantity of cannabis trim and cannabis flower, uniform in character and quality, from the same seed stock or cuttings taken from cannabis plants of the same genotype and phenotype, that has undergone the same propagation and cultivation processes, and harvested within a seventy-two hour period, in the same environment, and cured under the same conditions, or (2) a distinct group of cannabis product, uniform in character and quality, that has been produced in the same environment, under the same conditions, and from the same processes, equipment, and ingredients during the same cycle;

(41) "Homogenous" or "Homogenized" means uniform in cannabinoid and terpenoid concentration;

(68) "Sample" means a portion or part of a batch, the characteristics of which represent, as accurately as possible, the entire batch, allowing for the cannabis testing laboratory testing results of the sample to be generally applied to the entire batch;

Discussion:

Industry Study: A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis (Included as APPENDIX A) notes a statistically significant variance in microbial and potency results in three methods of evaluation:

- Within the the same cannabis batch
- When retesting the same sample
- When the same batch cannabis is tested in different labs
- Batch homogenization before testing— is an unfeasible standard given cannabis's natural heterogeneity.

Plant Heterogeneity: Cannabis is a complex botanical product with natural variability in composition. Heavy metals, including chromium, may accumulate differently across parts of the plant (e.g., roots, stems, and flowers), making representative sampling difficult.

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Homogeneity in Final Packaging

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Stability Concerns: FFT often requires that cannabinoid content remains within a specific percentage of the labeled claim over time (e.g., ±10%). Due to the natural degradation of cannabinoids and terpenes during storage, many products fail stability tests despite being safe and effective.

Time Frame: Due to FFT, products may not make it out the door before they need to be submitted for 30 and 60 day stability testing.

Potency Variability with Stability Testing and Conflicting Recovery Standards: The ±10% tolerance for cannabinoid concentrations at days 30 and 60 is unattainable due to natural variability in cannabis. Additionally, the state's recovery range (80–120%) for labs conflicts with stricter stability testing requirements (90–110%), increasing the risk of unjustified failures."By unnecessarily reporting results to the one-hundredth percentile, some labs created an unrealistic illusion of precision that raises false expectations regarding the degree to which accuracy is possible, given the 20% variation observed."
https://www.canorml.org/business-resources-for-cannabis-brands/how-accurate-is-cannabis-potency-testing/

Packaging Interference: Packaging materials can interact with the product during testing, introducing variables that skew results (e.g., THC adhering to certain plastics).

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Replace stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

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d. CHROMIUM TESTING

Regulations Proposed by DCP:

Section 21a-421j-29(i)(3):

- Cannabis samples must be tested for heavy metals, including chromium, to ensure compliance with the following thresholds:
  - Inhalation Route: ≤ 0.6 µg/g
  - Non-Inhalation Route: ≤ 2.0 µg/g
- These limits ensure the product is safe for consumption or use according to the intended delivery metho*d.*

Discussion: Chromium is not commonly tested in cannabis products across most states. This concern is better addressed through periodic monitoring within a comprehensive Hazard Analysis and Critical Control Points (HACCP) program rather than testing individual products. Such an approach allows for proactive identification and mitigation of contamination risks in cultivation environments.

However, we recognize the unique risks posed by vaporizable cannabis products, where chromium may accumulate in heating elements or delivery systems. These scenarios may require alternative considerations, including targeted testing or material-specific evaluations, to ensure consumer safety.

Differentiation of Chromium Species: Chromium exists in multiple oxidation states, primarily trivalent (essential and less toxic) and hexavalent (highly toxic). Accurately differentiating

between these species requires advanced instrumentation like inductively coupled plasma-mass spectrometry (ICP-MS) combined with specific sample preparation techniques.

During Processing: Chromium contamination can occur from processing equipment or packaging materials, leading to higher detected levels. For example, stainless steels (the gold standard for use in facilities can falsely elevate the detectable chromium levels due Chromium oxide which resides on the surfaces.

Complex Matrices: Cannabis samples contain organic compounds, cannabinoids, and terpenes that can interfere with heavy metal analysis. Proper sample digestion and matrix removal are crucial for accurate chromium detection.

Moisture Content: Variations in cannabis moisture levels can affect the concentration calculations of heavy metals in dry weight samples, introducing potential inaccuracies.

Equipment Calibration: Differences in the calibration of ICP-MS or atomic absorption spectrometers can result in inconsistent chromium measurements.

Lack of Standardized Limits: Chromium testing guidelines and permissible limits vary widely Some states or countries may not specify limits for chromium or differentiate between its forms.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.
- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

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e. OUT-OF SPECIFICATION (OOS) POLICY

Regulations Proposed by DCP:

Failed Microbiological Testing and Retesting Requirements

- If a cannabis sample does not yield satisfactory results during microbiological testing, the cannabis establishment must follow specific procedures:
    - Enter all analysis and test results into the Cannabis Analytic Tracking System.
    - Dispose of the cannabis sample according to Section 21a-421j-3 of the Regulations of Connecticut State Agencies.
    - Comply with retesting, remediation, and disposal provisions as outlined in Section 3 of Public Act 24-76.

Discussion:

Out-of-Specification (OOS) Policy: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory error

Lack of Retesting Policies: Unlike FDA and ICH guidelines, Connecticut mandates batch destruction after two failed tests, disregarding potential laboratory errors. This can cost operators tens of thousands of dollars per batch of failed testing.

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

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2. EXTENTION OF P&P TIMEFRAME OR EXPANDED REGULATION FLEXIBILITIES RESPONSIVE TO INDUSTRY CAPABILITIES

Regulations Proposed by DCP:

Discussion: Proposed regulations do not allow for urgent changes to cannabis operations and requirements. This is of great concern as many of the first round of licensees have not opened their businesses yet. This disregards the opportunity for the Department to gather information to guide the operations of these new license types.

P&P Time Frams Recommendations: Regulatory Recommendation: Extend the policies and procedures (P&P) review process for an additional 12 months or include a provision granting the Commissioner the authority to adapt regulations at their discretion based on emerging industry information and developments.

3. COMPREHENSIVE SUMMARY OF RECOMMENDATIONS

Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting these recommendations, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.To address these issues, we propose the following recommendations

Heterogeneity Recognition Recommendations:

- **Eliminate the Homogenization Requirement** recognize the scientific impossibility of homogenizing cannabis.
- **Update Definitions for Consistent Explanation** of expectation around homogenity
- **Account for the natural variability for results** when setting Laboratory Testing Standards

FFT Recommendations:

- **Employ Intermediate Bulk Testing (IBT):** Allows testing of larger, homogenized batches before final packaging, reducing costs and logistical challenges.
- **Randomized Sampling:** Testing randomly selected units from production batches can provide an accurate representation of product quality without testing every SKU.
- **Consider Periodic Testing of Packaging Products** to identify microbial or bioaccumalte concerns

Stability Testing Recommendations:

- **Revise stability testing standards**: Adjust the ±20% tolerance for potency, a scientifically anticipated range, AND
- **Time Frames:** Consider stability testing as an annual process to access critical control points. With FFT, products may not leave the facility until until after the 30 and 60 marks currently required for stability testing.

Chromium Recommendations:

- Chromium should be assessed periodically as part of a HACCP program to monitor trends over time and identify potential sources of contamination. This trend analysis would enable informed decisions about risk levels and mitigation strategies before implementing an unnecessarily strict standard. For vaporizable cannabis products, targeted testing or evaluation of heating elements may be necessary to address specific risks.

- Additional studies need to be conducted to understand which type of Chromium is present in the products and to determine appropriate standard levels prior to setting a standard.
- If the requirement cannot be lifted in the interim, consider raising using the same standard for inhalents and edibles of ≤ 2.0 µg/g

Out-Of Specification Recommendations: Adopt Food and Drug Administration-compliant Out of Specification Policies, allowing for retesting and investigation of anomalies before batch destruction.

P&P Time Frams Recommendations: Regulatory Recommendation: Extend the policies and procedures (P&P) review process for an additional 12 months or include a provision granting the Commissioner the authority to adapt regulations at their discretion based on emerging industry information and developments.

APPENDIX A

A Comparative Study of Same Lot Cannabis Product Testing THC and Microbial Analysis

INTRODUCTION: This study was conducted to better understand the variances in testing that can be seen in microbiology and potency test for cannabis flower. This study compares these factors across the batch, within the same sample, and between separate labs,

MATERIALS AND METHODS: A controlled study conducted at two labs analyzed 15 samples in duplicate, yielding 30 data points per lab, per test.

- 30 samples of Cannabis were selected from a single batch
- 2 separate labs received 15 samples of each
- Each lab tested 15 samples for THC and for 15 Micro
- Each lab tested lab tested their individual samples twice

RESULTS: Results confirmed substantial variability in cannabis testing:

- **Total THC Analysis**:
  - Lab 1: 11% range
  - Lab 2: 16% range
  - Duplicate results showed inconsistent outcomes, even for identical samples.
- **Total Yeast and Mold Analysis**:
  - Lab 1: 1,400–1,300,000 cfu/g
  - Lab 2: 1,100–471,000 cfu/g
  - Variability between replicates ranged up to several hundredfold.

DISCUSSION: These findings align with academic research documenting cannabis's inherent heterogeneity. Connecticut mandates batch homogenization before testing—an unfeasible standard given cannabis's natural heterogeneity. Additionally, the natural variability indicates that no single lab test is a cohesive representation of the sample.

CONCLUSION: Connecticut's current cannabis testing policies do not account for the natural variability of cannabis. By adopting the recommendations in the above proposal, the state can establish a fair, scientifically sound regulatory framework that ensures product quality without placing undue burdens on businesses.