Standardizing Cannabis Lab Testing Nationally

National Cannabis Laboratory Council (NCLC)

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EXECUTIVE SUMMARY

As the legal cannabis market continues to expand, and potential federal legalization and inevitable interstate commerce loom on the horizon, it is imperative that federal agencies address the discrepancies among state testing requirements and develop a standardized testing regime. Adoption of national standards will advance public health and safety goals while also facilitating interstate commerce of safe cannabis products.

The National Cannabis Laboratory Council (NCLC) proposes a unified approach to testing based on both data from participating laboratories and scientifically recognized standards. There is a need to transition from a state variable testing program to a harmonized testing scheme to create a baseline for quality testing of cannabis products and allow for interstate commerce while the industry transitions to risk-based testing programs designed by the cultivators and manufacturers. The group further suggests setting national standards governing (1) standard test panels setting forth specific compounds to include in an analysis, (2) sampling requirements and testing methodologies, and (3) lab accreditation and proficiency testing requirements.

Specifically, the authors propose harmonized standards for the following areas:

1. **Cannabinoid and Terpene Testing**
    a. For all products, the concentration of the following cannabinoids: ∆9-THC, ∆9-THCA, ∆8-THC, CBD, CBDA, CBG, CBGA, CBN, and CBNA.
    b. For all products, the concentration of the following cannabinoids if they are listed on the label: CBDV, CBDVA, THCV, CBL, ∆10-THC, Exo-THC, THC-O acetate, HHC, and any other cannabinoid on the label.
    c. Calculation of total THC, total CBD, and total cannabinoid concentration.
    d. For flower and pre-rolls, the concentration of the following terpenes: α-pinene, β-myrcene, β-caryophyllene, limonene, terpinolene.
    e. For all products, the concentration of any terpene listed on the label.

2. **Microbiological Contaminant Testing**
    a. Total Yeast and Mold (TYAM), pathogenic *Aspergillus*, *Salmonella*, Shiga toxin–producing *Escherichia coli* (STEC), and Total Coliforms testing in all products.
    b. Enhanced microbial testing for specialized products such as suppositories, nasal sprays, and inhalers.
    c. Aflatoxins (B1, B2, G1, G2) and ochratoxin A testing in all products.

3. **Chemical Contaminant Testing**
    a. Levels of Class I and Class II solvents in cannabis extracts, vaporizers, nasal sprays, and inhalers.
    b. Levels of Class III solvents and other solvents not included in U.S. Pharmacopeia (USP) general chapter <467> if intentionally added during manufacturing.
    c. Concentration of arsenic, cadmium, chromium, copper, lead, mercury, and nickel in inhaled products and arsenic, cadmium, lead, mercury, and nickel in all other products.

d. Use of risk-based recommendations from the U.S. Food and Drug Administration (FDA) for other elements if used in extracting or manufacturing, or if present as part of a device that can leach into extract.
e. Use of NCLC's list of the 80 pesticides detected in cannabis products and human health and toxicology data, when available, to create a federal panel.

4. Other Testing

a. Shelf stability testing to address the effects of packaging and storage conditions over time.
b. Water activity testing for flower, pre-roll, edible, and topical products.
c. Moisture content testing for flower and pre-roll products.

5. Testing Instrumentation, Methods, and Published Standards

a. Adoption of standard methodologies and instrumentations for testing cannabis as promulgated by organizations such as ASTM International, AOAC International, USP, and ISO/IEC.
b. Proficiency standards and accreditation requirements for testing labs, including ISO/IEC 17025 accreditation and participation in ISO/IEC 17043 accredited proficiency testing programs.
c. Implementation of federal guidelines for representative batch sampling, sample sizes, and frequency of testing.

INTRODUCTION

As of 2022, Cannabis is legal in 38 states, four territories, and the District of Columbia for medicinal use and in 19 states and D.C. for adult use. [1, 2] The popularity of smokable flower and a wide variety of finished cannabis products has soared, with a recent Pew Research Center poll finding that 91% of Americans support the legalization of cannabis.[3] A March 2022 report by BDSA noted that legal cannabis sales in the United States will surpass $28 billion in 2022 and are forecasted to reach approximately $46 billion by 2026.[4] However, the unsustainable federal-state conflict challenges the future of this growth, with the federal government continuing to categorize marijuana as having a "high potential for abuse" and lacking any "medicinal value."[5] Despite the classification of marijuana as a scheduled controlled substance, the federal government through the Department of Health and Human Services (DHHS) owns the patent on medical marijuana and has shown continued interest in the future medical uses of this plant.[6] Additionally, Congress has utilized appropriations bills to protect state medical marijuana programs from Department of Justice interference for nine years running. With Congress and DHHS taking actions that support the medical utility of cannabis, it is increasingly likely that cannabis will be descheduled under the Controlled Substances Act (CSA) at some point in the future.[7] The FDA has also approved multiple drugs containing cannabis, further indicating the strength in arguments that promote legalization and the medicinal properties in the plant.

Today, cannabis testing is performed according to the unique regulatory framework within each state that has legalized cannabis. In order to protect the public health and safety of consumers, and to realize the full potential of interstate trade, national testing standards must be developed and implemented federally. A critical component of this federal guidance will be a standardized approach to lab testing and the removal of existing state requirements that unnecessarily burden other states and out-of-state businesses. Under such a system, if a state imposes burdensome testing requirements, then it would be at risk of violating federal jurisprudence and rendering its requirements unenforceable.

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[1] The scope of this paper focuses on medical and adult-use marijuana. Policymakers involved in drafting hemp-derived product testing requirements are encouraged to address topics similar to those presented herein.

[2] *State Medical Cannabis Laws*, NATIONAL CONFERENCE OF STATE LEGISLATURES (Apr. 19, 2022), https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx.

[3] Ted Van Green, *Americans overwhelmingly say marijuana should be legal for recreational or medical use*, PEW RESEARCH CENTER (Apr. 16, 2021), https://www.pewresearch.org/fact-tank/2021/04/16/americans-overwhelmingly-say-marijuana-should-be-legal-for-recreational-or-medical-use/.

[4] BDSA, *BDSA Cannabis Market Forecast: Spring 2022 Update*, BDSA ESSENTIAL CANNABIS INSIGHTS (Mar. 2022), https://bdsa.com/wp-content/uploads/2022/03/Cannabis-Market-Forecast-Spring-2022-Update.pdf.

[5] CONG. RSCH. SERV., IN11204, THE SCHEDULE I STATUS OF MARIJUANA (Mar. 2022), https://crsreports.congress.gov/product/pdf/IN/IN11204.

[6] U.S. Patent No. 6,630,507.

[7] Marijuana is currently a Schedule I substance under the CSA, meaning that it has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

CANNABIS AND THE DORMANT COMMERCE CLAUSE: WHY STANDARDIZATION MATTERS FOR INTERSTATE COMMERCE

Pursuant to the Commerce Clause, Congress may "regulate commerce . . . among the several states."[8] The Constitution therefore provides an express grant of authority to Congress to regulate interstate commerce. Notably, there is no mention of any role for the states. Courts have interpreted the Constitution's language to mean that states are likewise prohibited from interfering with interstate commerce. This limitation on states' authority is known as the "dormant commerce clause" (DCC).

Because cannabis is federally illegal, the 38 states that have legalized medical marijuana have 38 very different regulatory structures in place. From distinct lab testing obligations to specific track-and-trace, packaging and labeling, and licensing requirements, each state has set its own course. These state regulatory structures exist independently and are largely born out of the dearth of federal oversight. Notwithstanding their critical importance to public health today, many of these state regulations could be in jeopardy once interstate commerce is unleashed in the cannabis industry due to the DCC.

Labeling the DCC as "essential to the foundations of the Union," the Supreme Court has found "in all but the narrowest circumstances, state laws violate the Commerce Clause if they mandate differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter."[9] Similarly, the Court has found that the DCC "prevents the States from adopting protectionist measures and thus preserves a national market for goods and services."[10]

When courts examine whether a state regulatory scheme violates the DCC, they apply one of two frameworks, depending on whether the challenged law is discriminatory on its face or in its practical effect. If the challenged law represents "economic protectionism," as measured by either "discriminatory purpose" or "discriminatory effect," then a court applies strict scrutiny review. Rules that have such a discriminatory purpose or effect will almost always be declared invalid by a court.[11] Given the high bar of strict scrutiny review, state mandates rarely succeed under this standard, as the state must demonstrate that the policy rationale behind the mandate could not be as well served by some other, nondiscriminatory means.[12]

If a challenged mandate is not discriminatory on its face, it may nonetheless be discriminatory in its practical effect and violate the DCC under the "*Pike* test."[13] Under *Pike*, a law that imposes only "incidental" burdens on interstate commerce is unconstitutional when the burden imposed on interstate commerce is clearly excessive in relation to the putative local benefits. Courts applying this *Pike* test have invalidated more apparently neutral state laws when these challenged state requirements would impose undue burdens on interstate commerce.[14]

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[8] U.S. CONST., art. I, § 8, cl. 3.

[9] *Granholm v. Heald*, 544 U.S. 460, 472, 125 S. Ct. 1885, 1895, 161 L. Ed. 2d 796 (2005).

[10] *Tennessee Wine & Spirits Retailers Ass'n v. Thomas*, 139 S. Ct. 2449, 2459 (2019).

[11] *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 471 (1981).

[12] *Maine v. Taylor*, 477 U.S. 131, 138 (1986) (upholding Maine's ban on importing baitfish when it served a legitimate public purpose, and that purpose could not have been served by nondiscriminatory means).

[13] *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

[14] *Kassel v. Consol. Freightways Corp. of Delaware,* 450 U.S. 662, 671–75 (1981) (invalidating state mandate concerning limitations on truck length).

This is likely the test that would be applied to cannabis lab testing standards mandated by any state, because such standards would necessarily affect the ability to import cannabis and sell it in a state, and therefore they would burden interstate commerce in practical effect.

For example, the Supreme Court previously examined whether an Illinois state law requiring a certain type of rear mudguard violated the DCC. The requirement of a particular mudguard, contoured or straight, was not facially discriminatory against out-of-state businesses. Even so, the Court held that the state regulation nonetheless placed unreasonable burdens on interstate commerce, especially when changing mudguards was a time-consuming task without any justifiable need for such a requirement.[15] While there is certainly a justifiable need for lab testing, inconsistent requirements for testing contaminants between states could plausibly be viewed by courts as placing an undue burden on interstate commerce. At the very least, this would likely translate into prolonged litigation against the state regulators who promulgated the rules. At the most, it could result in a federal court striking down any such lab testing rules as overly burdensome and a violation of the DCC. Either way, it would be a waste of time and resources for the state to have to defend, particularly when the work can be done—and done now—to harmonize testing regimes.

Any state regulations that hinder interstate commerce will face scrutiny post-descheduling and after implementation of interstate commerce.[16] This makes planning ahead critically important. Unless we do the work now to identify the most important testing requirements, we will be behind when federal legalization occurs, leaving both consumers and entrepreneurs at risk. Therefore, it is crucial that we act now to establish the baseline for national lab testing standards. This will be an imperative for federal regulators as we enter the next phase of legalization. For instance, when Senate Majority Leader Chuck Schumer circulated the Cannabis Administration and Opportunity Act in August of 2021, the bill contained provisions mandating a federal track-and-trace system as well as current Good Manufacturing Practices (cGMP). However, it would be impractical for federal regulators to establish a federal track-and-trace program without national lab testing standards. Likewise, it is hard to imagine how the federal government mandates cGMP if each state continues to have its own lab testing rules.

THE PRESENT STATE OF CANNABIS LAB TESTING

In 2014, Colorado became the first U.S. state to introduce mandatory compliance and safety testing for legalized cannabis products.[17] Since then, various panels for testing intermediate and final products have been introduced and subsequently required by most states with regulated cannabis markets. State-mandated testing programs were implemented, in part, to address the lack of quality standards (such as cGMP, GAP, and/or Quality Management Systems (QMS)) being used in cannabis cultivation and manufacturing facilities.

[15] *Bibb v. Navajo Freight Lines, Inc*., 359 U.S. 520, 529 (1959).

[16] Tommy Tobin & Andrew Kline, *A Sleeping Giant: How the Dormant Commerce Clause Looms Over the Cannabis Marketplace*, YALE LAW & POLICY REVIEW (Jan. 3, 2022), https://ylpr.yale.edu/inter_alia/sleeping-giant-how-dormant-commerce-clause-looms-over-cannabis-marketplace.

[17] 1 COLO. CODE REGS. §§ 212–1, 212–2.

While testing is only part of a cGMP or QMS program, it is a crucial component of developing a reliable and quality product and an important lever for regulators as the industry develops.[18] While the cannabis industry learns to incorporate cGMP in product manufacturing, many state regulators have added third-party testing requirements to their regulations ahead of requiring comprehensive cGMP, GAP, and/or QMS requirements. The goal of this testing is to facilitate accurate potency and terpene claims on product labels and avoid introducing harmful contaminants to patients and consumers. Additionally, this third-party testing is intended to assure patients and consumers that they are consuming cannabis products that meet the safety and quality standards set by their state regulators.

While cGMP and QMS focus on business-specific risk assessments of individual product lines to determine sampling plans, testing panels, and frequencies, state-mandated cannabis programs provide "one size fits all" testing regimes based on requirements from industries like environmental, food, and pharmaceuticals. With a lack of safety and toxicology data specific to the cannabis industry early on, this was believed to be the best approach available to state regulators. As is typical in other consumer products industries, it is highly likely that some sort of federal cGMP, GAP, and QMS requirements will be applied to cannabis. With relevant frameworks to reference, the cannabis industry can look to the decades-long process that other industries followed as they moved from segmented regulatory standards to federal cGMP requirements. The state-legal cannabis industry is still new in comparison; it will need more data and time to transition to federal cGMP implementation, and it will need a unified approach to get there.

All 38 states with medical cannabis programs impose some form of potency and/or contaminant testing requirements for legal marijuana products in their state. Another four states without regulatory frameworks for legal cannabis have some form of testing requirements for CBD oil.[19] However, the testing standards and methodologies vary significantly. For example, some states require testing for four cannabinoids (e.g., Arizona, Hawaii, Michigan, Oregon), while other states require testing for six or more cannabinoids (e.g., California, Florida, Maryland, Nevada, New York). Some require testing for several fungal and bacterial microorganisms (e.g., Colorado, Connecticut, Hawaii, Illinois, Oklahoma, Massachusetts and several more), and other states require no microbial testing at all (e.g., Oregon). Some states require testing for 13 pesticides (e.g., Colorado), and other states require testing for 66 pesticides (e.g., California).[20] In addition, there is significant variability in the permissible limits for contaminants within each state as well as the allowed variation between label claims and actual potency results as determined by a laboratory.

These standards become even more variable when incorporating hemp-derived consumer products containing cannabinoids other than Δ9-tetrahydrocannabinol (Δ9-THC) into the conversation. In some states this has led to the convergence of hemp and marijuana agencies under a cannabis umbrella (e.g., Michigan's newly formed Cannabis Regulatory Agency) and in others has even led to the prohibition of compounds such as Δ8-THC,

[18] A recent publication by FDA staff analyzed the testing requirements in state medical cannabis programs and those in the federal cGMPs for finished drug products, and emphasized the need for standardized testing protocols and methodologies to keep consumers safe. Schuyler A. Pruyn, et al., *Quality Standards in State Programs Permitting Cannabis for Medical Uses*, CANNABIS AND CANNABINOID RESEARCH (Mar. 28, 2022), https://www.liebertpub.com/doi/epub/10.1089/can.2021.0164.

[19] According to an independent review of all marijuana regulations across states, referenced from the website that houses each state's cannabis regulations, completed by NCLC in May 2022.

[20] According to an independent review of all marijuana regulations across states, referenced from the website that houses each state's cannabis regulations.

after regulators became aware of hemp-derived Δ8-THC that bypassed safety testing and age restrictions on sales (e.g., Oregon). Recently, the Ninth Circuit found that Delta 8 is considered federally legal pursuant to the plain language of the 2018 Farm Bill.[21] The court used the term "loophole" in its reasoning and specifically stated that it was for Congress to fix.[22] While it's possible that Congress will act, there is no certainty. Meanwhile, states will continue to regulate Delta 8 products as they deem most appropriate. For the purposes of establishing a harmonized national testing standard, the following discussion focuses on cannabis consumer products containing cannabinoids sold in the state-legal cannabis marketplace, and it intentionally excludes any standards or discussion of industrial hemp and other types of related products.

LOOKING FORWARD: A HARMONIZED APPROACH FOR TESTING CONSUMER CANNABIS PRODUCTS

As we embark on the next decade of cannabis legalization, it is critical that federal agencies address the discrepancies among state testing requirements and methodologies and develop a better understanding of the health and safety measures appropriate for cannabis based on consumption method. Federal oversight will provide state agencies with a baseline framework for defining, monitoring, and reporting results as they pertain to cannabis-related products. The first step in this federal framework is a harmonized testing panel that would simplify the process by which growers and manufacturers could expand operations given the likely introduction of interstate commerce.

Harmonization of testing methodologies would have the added benefit of limiting the opportunity for data manipulation and even fraud, which persists in virtually all legal cannabis markets. In the current system, cannabis testing labs are under significant pressure to produce favorable results for their clients; with the disjointed and sometimes unenforceable state regulatory frameworks, these practices have gone largely unchecked and even, at times, have been inadvertently encouraged (e.g., inflated potency results, inaccurate chemical contamination profiles).

As the cannabis industry continues to mature, standard-developing organizations, such as USP, AOAC International, and ASTM International, have been recognizing methods of analysis to satisfy the testing requirements outlined by various state regulations. Adoption of standardized industrial methods similar to other industries, such as food and pharmaceuticals, will help the cannabis industry produce a product that meets the consumer's needs of product quality and safety.

The goal of this paper is to recommend a harmonized approach for testing consumer products containing cannabinoids that will allow the industry to transition from variable requirements per state to a national risk-based program. These suggestions for a unified testing program are based on the combined data of labs with locations in more than a dozen states.[23] The authors combined data on compounds detected by their laboratories as a baseline in determining which compounds may be present in cannabis products. The following recommendations also consider the viewpoint of organizations such as the USP, which recently published

[21] B. Cohen, et al., "Ninth Circuit Rules on Legality of Delta-8 THC Products," CANNABIS LEGAL HIGHLIGHTS: THE 411 ON 420 (May 20, 2022), https://www.cannabislegalhighlights.com/2022/05/ninth-circuit-rules-on-legality-of-delta-8-thc-products/.

[22] *AK Futures LLC v. Boyd Street Distro, LLC*, No. 21-56133 (9th Cir., May 19, 2022), https://cdn.ca9.uscourts.gov/datastore/opinions/2022/05/19/21-56133.pdf.

[23] The authors represent cannabis testing laboratories with locations in Arizona, California, Colorado, Florida, Illinois, Massachusetts, Michigan, Nebraska, Nevada, New York, Oregon, South Dakota, and Tennessee.

recommended quality specifications for cannabis flower,[24] as well as data from other industries on contaminants known to cause adverse health effects. While there are limited published case studies and toxicity data on the harms of contaminants in cannabis products specifically, it is reasonable to assume certain similarities in adverse health effects, such as effects caused by consuming a pesticide-contaminated vegetable or inhaling metal from a nicotine e-cigarette. Additionally, the recommendations in this paper may be used as a baseline for enabling interstate commerce so that consumers and regulators can be assured that products are tested for the same compounds regardless of the product's state of origin while the industry gains more experience to eventually implement cGMP and QMS.

[24] Nandakumara D. Sarma, et al., *Cannabis Inflorescence for Medical Purposes: USP Considerations for Quality Attributes*, 83 J. OF NAT. PRODUCTS 1334 (2020), https://pubs.acs.org/doi/abs/10.1021/acs.jnatprod.9b01200.

POTENCY TESTING

Potency in cannabis plant materials and products is defined by the concentration of Δ9-THC and other cannabinoids. At the federal level, the concentration of Δ9-THC synthesized and stored by the plant (below or above 0.3% on a dry weight basis) is the only distinction between *Cannabis sativa L.* classified as hemp versus that classified as marijuana grown for medical and adult use, as defined by the 2018 Farm Bill. The U.S. Department of Agriculture (USDA) further requires that total THC levels must be evaluated after decarboxylation or mathematical compensation for ∆9-tetrahydrocannabinolic acid (Δ9-THCA), the form naturally found in the plant that is a precursor to Δ9-THC but is not itself psychoactive.

In addition to ∆9-THC, many other cannabinoids are being marketed for a variety of purposes including asserted medicinal properties. These label claims make it important for certain cannabinoids to be included in a minimum list for potency testing. Today, cultivators are breeding cannabis varieties to increase the natural concentration of minor cannabinoids (e.g., CBG, CBC), with the main difference between minor cannabinoids and Δ9-THC and isomers of Δ9-THC being the psychoactive response.

Recently, chemical derivatives including isomers of Δ9-THC and CBD currently not found naturally at high levels in the plant have also been introduced to the market. To make large quantities of these compounds, high abundance natural cannabinoids (i.e., Δ9-THC and/or CBD) are chemically converted in a laboratory to a synthesized compound. No safety data currently exists to prove that harmful chemicals used in the synthesis are not carried over into products or that harmful byproducts are not created. This leads to two challenges for regulators and testing laboratories alike. First, to identify and quantify these synthetic and semi-synthetic cannabinoid derivatives, suitable analytical methods and certified reference materials must be available; second, the synthesis process may generate other uncharacterized analogues and side products that may vary due to insufficient production controls and not be removed during the production process and may not be identifiable due to the absence of these compounds on any regulated panel.

Predicting how these synthetic and semi-synthetic cannabinoids and their possible side products might affect biological activity and safety for human use is difficult, thus putting public safety at risk. Among those currently being widely marketed are ∆8-THC, ∆10-THC, ∆9,11-THC (exo-THC), acetylated THC (THCO acetate), and hexahydrocannabinol (HHC). Further, studies are starting to report safety risks when using products with brominated or acetylated cannabinoids that are likely synthesized rather than extracted from the cannabis plant (e.g., ketene gas formation upon vaping THCO acetate[25]). As such, NCLC recommends policymakers add synthetic cannabinoids to the standard required cannabinoid panel. The rapid pace at which these synthetic cannabinoids have appeared in the market points to the need for regular review and modification of this list. However, until then, at a minimum, any cannabinoid listed on the label should be required to be part of the potency testing panel.

[25] Kaelas R. Munger, et al., *Vaping Cannabinoid Acetates Leads to Ketene Formation*, ChemRxiv (2022), https://chemrxiv.org/engage/api-gateway/chemrxiv/assets/orp/resource/item/6271c003d048edf65f5b45d9/original/vaping-cannabinoid-acetates-leads-to-ketene-formation.pdf.

NCLC recommends that the following cannabinoids be included in a standardized potency panel for all products:

- Δ9-THC
- Δ9-THCA
- Δ8-THC
- CBD
- CBDA
- CBN
- CBNA
- CBG
- CBGA

Further, the group recommends that any cannabinoid on the label should be required to be on the cannabinoid testing panel for all products, such cannabinoids to include, but not be limited to, the following:

- CBDV
- CBDVA
- THCV
- THCVA
- CBL
- CBLA
- CBC
- CBCA
- ∆10-THC
- ∆9,11-THC
- THCO acetate
- HHC

CALCULATING CANNABINOID CONTENT

NCLC recommends that laboratories calculate and report total cannabinoid content, total THC, and total CBD for any material or product containing cannabinoids. Total cannabinoid content is defined as the summation of any identified and quantified cannabinoid at or above the Limit of Quantification (LOQ), which is the lowest level of a compound that can be quantified. Non-carboxylated and acidic forms should be reported separately if they are distinguishable by the validated analysis method.

For total THC and total CBD calculations in plant materials and concentrates that may be subject to high heat during consumption, NCLC recommends using the calculation that accounts for decarboxylation and weight loss when that happens.

Total THC = THC + (0.877 x THCA)

Total CBD = CBD + (0.877 x CBDA)

Other groups suggest that any cannabinoid that has an acidic counterpart can have its total calculated by multiplying the amount of the acidic form by 0.877 and adding it to the amount of the decarboxylated form.[26] This is because the weight of ∆9-THC is 87.7% of that of ∆9-THCA. However, a different multiplier should be used for cannabinoids other than ∆9-THC and CBD as the molecular masses are not the same. For example, the calculation for total THCV is most accurately depicted as follows:[27]

Total THCV = THCV + (0.867 * THCVA)

Some scientists use different equations to determine total THC and total CBD content more accurately. When acidic cannabinoids are decarboxylated, not only does the molecule lose weight, but the total weight of the product is altered as well. To accommodate for the weight loss of the product, the weight lost from the Δ9-THCA or CBDA molecule can theoretically be subtracted from the product weight in the denominator, as seen in the following equations. NCLC does not recommend using these equations at this time, because they warrant more

[26] *Guide to a Harmonized National Laboratory Accreditation Program,* INDEPENDENT LABORATORIES INSTITUTE (2021), https://cdn.ymaws.com/www.acil.org/resource/resmgr/cannabis/guide_to_a_harmonized_nation.pdf.

[27] *Why 0.877?*, CONFIDENCE ANALYTICS LABORATORY (Feb. 10, 2016), https://www.conflabs.com/why-0-877/.

investigation. One possible flaw is that the equations do not account for possible weight loss from other molecules during heating, which may also affect the product weight.

Total THC = ((0.877 x ∆9-THCA) + ∆9-THC) / (product weight − 0.123 x ∆9-THCA)[28]

Total CBD = ((0.877 x CBDA) + CBD) / (product weight − 0.123 x CBD)

For non-inhaled, non-heated products, NCLC does not recommend accounting for decarboxylation in the final product. For example, if an edible has a Δ9-THCA concentration above the LOQ, it should be included in the results as Δ9-THCA, not contributing to total THC, as it is not intended to be heated and the Δ9-THCA molecule will not be decarboxylated.

[28] Markus Roggen, *Totally Miscalculated: The Total THC Problem*, THE CANNABIS SCIENTIST (Jan. 11, 2022), https://thecannabisscientist.com/testing-processing/totally-miscalculated-the-total-thc-problem.

TERPENE TESTING

Terpenes are aromatic compounds found in many plants, including cannabis, and are responsible for the various scents that are expressed naturally in cannabis inflorescence (i.e., the flower of the plant). Notes of citrus, lavender, earth, and "gas" are common topics of discussion between budtenders and consumers in dispensaries. Manufacturers regularly add terpenes into concentrate and edible products to craft and enhance flavor. Aside from giving cannabis products their unique aroma profiles, terpenes have a major influence on the consumer's experience.

Research has found that cannabis labeling (e.g., sativa, indica) was associated with variation in a small number of terpenes.[29] The presence of terpenes modulates the effects that the classic cannabinoids, such as Δ9-THC, have on the consumer's experience. This has classically been referred to as the "entourage effect."[30,31]

Although terpenes are considered Generally Recognized as Safe (GRAS) for use in supplements and herbal products, it is uncertain whether the same can be said for products that involve combustion/heating and subsequent inhalation, as occurs while smoking or vaping. Research shows that heating some marijuana products at high temperatures is associated with higher levels of harmful or potentially harmful components.[32]

NCLC recommends, at a minimum, five of the most common terpenes be required to be tested for in flower and pre-rolls: α-pinene, β-myrcene, β-caryophyllene, limonene, and terpinolene. The group also recommends that any label claim for total terpenes or individual terpenes be required to be supported by testing results. Terpenes may be integral to the medicinal relief patients experience when consuming cannabis. The research in this field is an evolving topic, and more than 150 terpenes have been identified in cannabis plants.[33] Therefore, the group further recommends that (1) cannabis cultivators and manufacturers voluntarily test for as many terpenes as possible and (2) policymakers continually reconsider required terpene testing panels.

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[29] Sophie Watts, et al., *Cannabis labelling is associated with genetic variation in terpene synthase genes*, 7 NATURE PLANTS 1330 (2021), https://www.nature.com/articles/s41477-021-01003-y.

[30] S. Ben-Shabat, et al., *An entourage effect: inactive endogenous fatty acid glycerol esters enhance 2-arachidonoyl-glycerol cannabinoid activity*, 353 EUROPEAN J. OF PHARMACOLOGY 23 (1998), https://pubmed.ncbi.nlm.nih.gov/9721036/.

[31] Ethan B. Russo, *Taming THC: potential cannabis synergy and phytocannabinoid-terpenoid entourage effects*, 163 BRITISH J. OF PHARMACOLOGY 1344 (Aug. 2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3165946/.

[32] Jiries Meehan-Atrash, et al., *The influence of terpenes on the release of volatile organic compounds and active ingredients to cannabis vaping aerosols*, 11 RSC ADVANCES 11714 (2021), https://pubs.rsc.org/en/content/articlehtml/2021/ra/d1ra00934f.

[33] Judith K. Booth & Jörg Bohlmann, *Terpenes in Cannabis sativa – From plant genome to humans*, 284 J. OF PLANT SCI 67 (Jul. 2109), https://www.sciencedirect.com/science/article/pii/S0168945219301190.

MICROBIAL AND MYCOTOXIN TESTING

All consumable product manufacturing processes run the risk of microbial and mycotoxin (toxic substances produced by fungus) contamination due to the ubiquity of microorganisms in our environment. These risks are known, frequent, and manageable. Within cannabis products, the risk of specific microorganisms being present in products varies by the category of products, as different categories have unique manufacturing processes and modes of consumption.

Table A details the National Cannabis Laboratory Council's recommendations for a federally harmonized approach to microbial and mycotoxin testing in consumer products containing cannabinoids based on the possibility that a particular microbial contaminant could be present, the previously documented severity of health issues related to that contaminant, and what microbes NCLC lab scientists have seen in cannabis products.

Based on the above criteria, NCLC's recommendation is to include testing for Total Yeast and Mold (TYAM), pathogenic *Aspergillus*, *Salmonella,* Shiga toxin–producing *Escherichia coli* (STEC), Total Coliforms, aflatoxins, and ochratoxin A in all cannabis products. In addition, supplementary microbial tests are recommended to be required for suppositories, nasal sprays, and inhalers, as these products are designed to have their components delivered deep in human organ systems, thereby warranting more comprehensive microbial testing requirements.

TABLE A. RECOMMENDATIONS FOR HARMONIZED MICROBIAL AND MYCOTOXIN TESTING REQUIREMENTS

Test	Flower, Pre-Rolls	Infused Pre-Rolls	Concentrates & Vaporizers	Edibles & Drinks	Tinctures	Topicals	Supplements, Pills, Capsules	Suppositories	Nasal Sprays, Inhalers
TYAM	X	X	X	X	X	X	X	X	X
Aspergillus	X	X	X	X	X	X	X	X	X
Salmonella	X	X	X	X	X	X	X	X	X
STEC	X	X	X	X	X	X	X	X	X
Total Coliforms	X	X	X	X	X	X	X	X	X
P. aeruginosa								X	X
S. aureus								X	X
C. albicans								X	
Total Aerobic Plate Count								X	X
Total Gram-Negative Bacteria								X	X
Aflatoxin B1, B2, G1, G2	X	X	X	X	X	X	X	X	X

Test	Flower, Pre-Rolls	Infused Pre-Rolls	Concentrates & Vaporizers	Edibles & Drinks	Tinctures	Topicals	Supplements, Pills, Capsules	Suppositories	Nasal Sprays, Inhalers
Ochratoxin A	X	X	X	X	X	X	X	X	X

While the microbial testing recommendations do not include testing for every possible microorganism that could be present, they include the pathogens most likely to be present in cannabis-derived products, based on what NCLC labs have detected. Table A also includes tests for quality indicator organisms, such as the TYAM test, which provide information on the total fungal population, and Total Aerobic Plate Count, which measures the total bacterial population in a sample. While monitoring for quality indicator organisms may not indicate the presence of specific pathogenic organisms, these tested organisms can have significant effects on taste, aroma, texture, and color and can also impact shelf stability.

It is important to note that one major challenge of microbial testing is the need for a statistically representative sample, or a recognition that the results may be more reflective of the sample taken than the batch as a whole. Since microbial contamination is rarely homogenous or uniform in a batch of product, a sample could have no harmful microbes detected and yet represent a batch in which those same microbes were present elsewhere. Controlling for this naturally occurring heterogeneity makes sample size a critical factor in the reliability of testing.

RESIDUAL SOLVENT TESTING

Recent studies have suggested that greater than 80% of cannabis concentrates contain residual solvents.[34] Residual solvents typically enter the manufacturing chain during the cannabis extraction process. Solvents such as propane, butane, and other hydrocarbons, as well as water, ethanol, isopropanol, acetone, and hexane, are commonly employed during cannabis flower extractions.[35] These solvents are typically cheap, easy to use, and exist in both licensed and illicit extraction facilities.[36,37,38] Terpene fractions added back into cannabis products for flavoring can also contribute to residual solvent contamination.

Most of the published residual solvents test regulations reference USP general chapter <467>, which is a standard for pharmaceutical products.[39] Even though the manufacturing of consumer products containing cannabinoids differs from pharmaceuticals, especially with the heavy reliance on hydrocarbon extractions, the health implications of consuming residual solvents at significant levels is the same.

Most residual solvents are divided into three categories based on their health concerns. Class I compounds are the most toxic, should be avoided in manufacturing processes, and have concentration limits around 1 ppm. Class II compounds are toxic, should be limited in manufacturing processes, and have concentration limits ranging from 290 to 5000 ppm. Class III compounds have lower toxicity, less risk to human health than Class I and II compounds, and concentration limits can be higher.[40]

For residual solvents, NCLC recommends requiring testing for Class I and II solvents in solvent-based concentrates, infused pre-rolls containing solvent-based concentrates, vaporizers, nasal sprays, and inhalers. This is due to possible toxicity and because these products involve solvents in their manufacturing or have solvents in their ingredients list.

Further, for Class III solvents, the group recommends testing be required to check for levels in final products only if the solvent was intentionally added or had the potential to be added during manufacturing. However, since Class III solvents are the least harmful in the class series, the risk of them being introduced to a product

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[34] Nicholas Sullivan, et al., *Determination of Pesticide Residues in Cannabis Smoke*, J. OF TOXICOLOGY (2013), https://www.hindawi.com/journals/jt/2013/378168/.

[35] Lee Marotta, et al., *Fast, Quantitative Analysis of Residual Solvents in Cannabis Concentrates*, PERKINELMER (2018), https://gcms.labrulez.com/labrulez-bucket-strapi-h3hsga3/paper/APP_Residual_Solvents_in_Cannabis_Concentrates_014321_01.pdf.

[36] Nate Seltenrich, *Cannabis Contaminants: Regulating Solvents, Microbes, and Metals in Legal Weed*, 127 ENV'T. HEALTH PERSPECTIVES (Aug. 20, 2019), https://ehp.niehs.nih.gov/doi/full/10.1289/EHP5785.

[37] L. L. Romano, *Cannabis oil: Chemical evaluation of an upcoming cannabis-based medicine*, 1 CANNABINOIDS (2013), https://www.researchgate.net/publication/297707359_Cannabis_oil_Chemical_evaluation_of_an_upcoming_cannabis-_based_medicine.

[38] Kelly Tatera, *Residual Solvent Analysis: Ensuring the Safety of Cannabis Extracts*, ANALYTICAL CANNABIS (Jun. 1, 2017), https://www.analyticalcannabis.com/articles/residual-solvent-analysis-ensuring-the-safety-of-cannabis- extracts-28902.1.

[39] United States Pharmacopoeial Convention, *<467> Residual Solvents* in UNITED STATES PHARMACOPEIA – NATIONAL FORMULARY (2022), https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/generalChapter467Current.pdf.

[40] CAL. CODE REGS. tit. 16, § 5718, https://bcc.ca.gov/law_regs/cannabis_order_of_adoption.pdf.

through an input or ingredient with trace contamination (i.e., an unintentional source) and causing adverse health effects is not as severe.

The recommendations for unified solvent testing requirements are presented in Table B.

TABLE B. RECOMMENDATIONS FOR HARMONIZED SOLVENT TESTING REQUIREMENTS

Test	Infused Pre-Rolls	Concentrates	Vaporizers	Flower, Pre-Rolls; Edibles& Drinks; Tinctures; Topicals; Supplements; Pills; Capsules; Suppositories	Nasal Sprays, Inhalers
Residual Solvents (Classes I and II)	X *(if includes a solvent- based concentrate)*	X *(for solvent- based concentrates only)*	X		X
Residual Solvents (Class III)	Test for any Class III residual solvent in any product that was intentionally added during manufacturing/processing.				
Residual Solvents not on USP 467 list	Test for any residual solvent in any product that is not included in the USP general chapter <467> list and was intentionally added during manufacturing/processing.				

ELEMENTAL IMPURITY TESTING

The terminology for elemental impurity testing, formerly known as heavy metal testing, was changed by USP to include all elemental contaminants that could be introduced in creating finished products.[41] Toxic elements with densities greater than 5g/cm^3 and atomic numbers higher than 11 have traditionally been called heavy metals.[42] Of the 90 naturally occurring elements, 53 can be classified as metals (and one metalloid, As).[43] These elements include lead, cadmium, arsenic, mercury, cobalt, vanadium, nickel, lithium, antimony, barium, molybdenum, copper, tin, and chromium, among others. Low concentrations of these metals (lower even than 0.01mg/L) have been shown to be toxic to humans. Some of these elements are essential plant nutrients (Cr, Mn, Mo, Zn, Fe, Co, Cu, Al, Ni), and some are nonessential elements that can lead to toxicity even at trace levels (Cd, Pb, As, Hg).[44,45] Many elements exist in different oxidation states and will have different biological impacts depending on their route of exposure; inhalation versus ingestion of cannabis products is an excellent example of this, as is the relative toxicity of Cr^6þ versus Cr^3þ.

Elements are present in the Earth's crust in varying concentrations and appear in food and cannabis products through plant bioaccumulation, cross contamination during processing, or post-process adulteration.[46] Elements can contaminate soil through runoff from industrial manufacturing plants, direct applications of fertilizers and pesticides, the application of animal wastes or sludges, and the atmospheric deposition of metal-containing particulate matter. It is also known that wildfires and volcanic eruptions in one location can deposit heavy metal containing ash on crops hundreds of miles away.[47]

Given the high toxicity of metals and other elements at low concentrations, it is important to quantitate them at low levels (parts-per-billion or lower). Common methods to prepare samples historically included the addition of concentrated acid followed by heating, such as Environmental Protection Agency (EPA) methods 200.2,

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[41] *Elemental Impurities: Standards-Setting Record*, USP (Dec. 2012), https://www.usp.org/sites/default/files/usp/document/our-work/chemical-medicines/key-issues/2012-12-20_elemental_impurities_standards-setting_record-full.pdf.

[42] Mohamed Lamine Sall, et al., *Toxic Heavy Metals: Impact on the Environment and Human Health, and Treatment with Conducting Organic Polymers, A Review*, 27 ENV'T. SCI. POLLUTION RSCH. 29927 (2020), https://link.springer.com/article/10.1007/s11356-020-09354-3.

[43] Zeeshanur Rahman & Ved Pal Singh, *The Relative Impact of Toxic Heavy Metals (THMs) (Arsenic (As), Cadmium (Cd), Chromium (Cr)(VI), Mercury (Hg), and Lead (Pb)) on the Total Environment: An Overview*, 191 ENV'T. MONITORING AND ASSESSMENT 419 (Jun. 8, 2019), https://pubmed.ncbi.nlm.nih.gov/31177337/.

[44] Anna Filipiak-Szok, et al., *Determination of Toxic Metals by ICP-MS in Asiatic and European Medicinal Plants and Dietary Supplements*, 30 J. TRACE ELEMENTS IN MED. AND BIOLOGY 54 (Apr. 2015), https://pubmed.ncbi.nlm.nih.gov/25467854/.

[45] Jillian E. Gall, et al., *Transfer of Heavy Metals through Terrestrial Food Webs: A Review*, 187 ENV'T. MONITORING AND ASSESSMENT 201 (2015), https://link.springer.com/article/10.1007/s10661-015-4436-3.

[46] Laura M. Dryburgh, et al., *Cannabis Contaminants: Sources, Distribution, Human Toxicity and Pharmacologic Effects*, 84 BRITISH J. OF CLINICAL PHARMACOLOGY 2468 (Nov. 2018), https://pubmed.ncbi.nlm.nih.gov/29953631/.

[47] Lakshmi Narayana Suvarapu & Sung-Ok Baek, *Determination of Heavy Metals in the Ambient Atmosphere*, 33 TOXICOLOGY AND INDUSTRIAL HEALTH 79 (2017), https://pubmed.ncbi.nlm.nih.gov/27340261/.

200.7, or 200.8.[48,49,50] However, high-throughput laboratories more commonly digest material in microwaves (microwave digestion). Many traditional methods to detect metals have included atomic absorption spectrometry, x-ray fluorescence, and proton-induced x-ray emission, but they struggle to meet detection limits.[51] More common methods in today's laboratories are inductively coupled plasma (ICP) with either optical emission spectrometry (ICP-OES) or mass spectrometry (ICP-MS). Due to many stringent testing requirements for heavy metals, ICP-MS has become the preferred technique, as it enables higher throughput, can reach lower detection limits, can detect multiple elements concurrently, and has a larger linear range than ICP-OES.

Given the propensity for cannabis plants to accumulate metals from contaminated soils[52], the problem of potential metal contamination is unlikely to go away soon. Unlike certain other testing categories, elemental impurities have reliable reference materials available and currently utilized by food and pharmaceutical markets certified by the National Institute of Standards and Technology (NIST) for lead, cadmium, arsenic, mercury, beryllium, cobalt, vanadium, chromium, manganese, molybdenum, nickel, selenium, and uranium.[53]

For elemental impurities, NCLC based its recommendations on those of other expert panels, such as the Independent Laboratories Institute (ILI) and the USP. For a detailed comparison of NCLC's recommendations with those of ILI and USP, see **Appendix C**. NCLC also relied on the FDA's ICH Q3D(R1) guidelines for elemental testing in drug products.[54] The FDA guidance is based on risks of specific elemental contamination through different consumption modes, including oral, inhalation, and parenteral. It is reasonable to suggest that the health and safety risks of consuming toxic elements by inhalation through FDA-approved drugs is equivalent to the risks when consuming them through inhalable cannabis products.

Thus, NCLC recommends, at a minimum, required testing for the following elements in inhalable products:

- Arsenic
- Cadmium
- Chromium

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[48] *Method 200.7 Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry*, U.S. EPA (1994), https://www.epa.gov/esam/method-2007-determination-metals-and-trace-elements-water-and-wastes-inductively-coupled-plasma.

[49] *Method 200.8: Determination of Trace Elements in Waters and Wastes by Inductively Coupled Plasma – Mass Spectrometry (Revision 5.4)*, U.S. EPA (1994), https://www.epa.gov/sites/default/files/2015-06/documents/epa-200.8.pdf.

[50] *Method 200.2: Sample Preparation Procedure for Spectrochemical Determination of Total Recoverable Elements (Revision 2.8)*, U.S. EPA (1994), https://www.epa.gov/sites/default/files/2015-08/documents/method_200-2_rev_2-8_1994.pdf.

[51] Nasir Ali, et al., *Growth Stage and Molybdenum Treatment Affect Cadmium Accumulation, Antioxidant Defence and Chlorophyll Contents in Cannabis sativa Plant*, 236 CHEMOSPHERE 124360 (Dec. 2019), https://pubmed.ncbi.nlm.nih.gov/31545186/.

[52] Rabab Husain, et al., *Enhanced Tolerance of Industrial Hemp (Cannabis sativa L.) Plants on Abandoned Mine Land Soil Leads to Overexpression of Cannabinoids*, 29 PLOS ONE e0221570 (Aug. 29, 2019), https://pubmed.ncbi.nlm.nih.gov/31465423/.

[53] *About NIST Standard Reference Materials*, NIST (August 25,2016), https://www.nist.gov/srm/about-nist-srms.

[54] *G3D(R1) Elemental Impurities: Guidance for Industry*, FDA (Mar. 2020), https://www.fda.gov/media/135956/download#page=15; Committee for Human Medicinal Products, *ICH Guideline Q3D (R1) on elemental impurities*, EUROPEAN MEDICINES AGENCY (Mar. 28, 2019).

- Copper
- Lead
- Mercury
- Nickel

For all other products, the group recommends, at a minimum, required testing for the following elements:

- Arsenic
- Cadmium
- Lead
- Mercury
- Nickel

Other elemental impurities should be considered in testing panels in alignment with FDA guidance for drug products according to the mode of consumption. If other elements are intentionally added during manufacturing processes or have the potential to be present (e.g., if they are a component of a vaporizer device), there should be confirmation that harmful levels are not in final products. Accordingly, NCLC recommends that the following elements should be considered for testing

- Antimony
- Barium
- Cobalt
- Gold
- Iridium
- Lithium
- Molybdenum
- Osmium
- Palladium
- Platinum
- Rhodium
- Ruthenium
- Selenium
- Silver
- Thallium
- Tin
- Vanadium

PESTICIDE TESTING

In the United States, pesticides are regulated by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[55] FIFRA classifies pesticides into three categories: conventional pesticides, antimicrobial pesticides, and biopesticides. Conventional pesticides are broadly characterized as being synthetically produced compounds that function to kill, deter, or otherwise mitigate the effect of a pest on a plant. Antimicrobial pesticides are disinfectants used to sanitize or reduce the growth and viability of microorganisms on hard surfaces, during the manufacturing process, or in water or other substances. Finally, biopesticides are produced from natural materials including plants, microorganisms, and some minerals.

Conventional pesticides and biopesticides are of specific interest to crop growers because of their utility in mitigating the effects of pests on a crop. Prior to being sold, all pesticides must be approved by the EPA for a specific use—targeting pest(s) on a specific crop or crop group. By law, uses are specified on the product label and include the following disclaimer: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." As an illegal plant at the federal level, cannabis presents a problem for pesticide developers and manufacturers, as they are not able to perform the necessary FIFRA-required testing to register a pesticide for use on cannabis. As there is no label-stipulated use on cannabis for any EPA-regulated pesticide, using EPA-regulated pesticides on cannabis is illegal, and the burden of studies representing the safety of various pesticides on cannabis is unmet. Some states (e.g., Oregon) have taken the approach of allowing use of pesticides that are exempt from EPA tolerance levels (i.e., the level of pesticide residues that are allowed on a crop).[56]

State cannabis regulatory agencies have responded to this lack of EPA registration by requiring testing for the presence of pesticides across some or all product categories. With over 400 biopesticides and over 1,700 conventional pesticides listed by the EPA,[57] exhaustive testing for the absence of all pesticides is not feasible, leaving significant state-to-state variability in testing requirements for pesticides. As an example, Massachusetts has a list of 9 pesticides, whereas Oregon requires cannabis to be tested for 59 pesticides. This issue of varying panels is further exacerbated by significant state-to-state variability in action levels—with up to three orders of magnitude difference in some pesticide action limits.

In preparation for federal legalization of cannabis, a common approach to pesticide testing should be considered, focusing on which pesticides to test and the action limit for each. Data gathered from 15 NCLC

[55] *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Facilities*, U.S. EPA (Mar. 28, 2022), https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities#:~:text=The%20Federal%20Insecticide%2C%20Fungicide%2C%20and,pesticides%20in%20the%20United%20States.

[56] *Oregon Cannabis: Cannabis and Pesticides*, OREGON DEPARTMENT OF AGRICULTURE (Apr. 2018), https://www.oregon.gov/oda/shared/Documents/Publications/PesticidesPARC/CannabisPesticides.pdf.

[57] *Pesticide Chemical Search*, U.S. EPA, https://ordspub.epa.gov/ords/pesticides/f?p=CHEMICALSEARCH:1:0::NO:1:: (expand "Filter by Pesticide Type" dropdown and select "Conventional Chemical" or "Biopesticides" to pull up lists)(last visited May 25, 2022).

labs[58] indicates a set of 29 pesticides that have been detected in samples from more than three states (in total, the labs have detected 80 pesticides on cannabis flower samples). See **Appendix B** for more information. This list represents a starting point for regulatory guidelines and is not intended to be inclusive of all pesticides that could be used by future operators or those looking to circumvent testing.

Upon federal legalization, registering an existing pesticide for use on cannabis would require going through the EPA registration process in addition to testing for efficacy and toxicological, and environmental liabilities.[59] Currently, 59 pesticides are approved for use on hemp (a single conventional pesticide and 58 biopesticides) and they could reasonably be approved for use on cannabis, since hemp and marijuana originate from the same plant species.

Because of the lack of cannabis consumption data, states have created required pesticide testing panels based on guidelines from the EPA, other industries, and, sometimes, data from their state departments. For example, California developed its list and action levels based on evidence from the state's Department of Pesticide Regulation, which has significant expertise in toxicology and human-health risk assessment. Even though Canada has fully legalized cannabis and theoretically has fewer barriers to performing research, the country also has a pesticide list not based on data specific to cannabis consumption; rather, Canada created its list by looking at the U.S. state requirements.[60]

Given that there are no federally approved pesticides in cannabis, and current pesticide panels do not take into account inhalation as the mode of consumption, NCLC does not recommend a list that exists already; instead, NCLC recommends that (1) regulators follow a procedure to regulate pesticides in cannabis (similar to that used by the EPA to regulate pesticides in other industries) with additional consideration for the unique nature of inhalable products such as flower, pre-roll, concentrates, vaporizers, nasal sprays, and inhalers, and (2) action limits be determined based on human health assessments and toxicology data specific to the use of cannabis products.

NCLC recommends that pesticide testing be required in flower, pre-rolls, and concentrate products. The group would not recommend pesticide testing in orally or topically consumed products, as non-cannabis-derived ingredients have their own pesticide regulations.

[58] The authors represent 15 cannabis labs located across 13 states: Arizona, California, Colorado, Florida, Illinois, Massachusetts, Michigan, Nebraska, Nevada, New York, Oregon, South Dakota, and Tennessee.

[59] Environmental drift contamination may result in the presence of other unapproved pesticide residue. Nadakumara D. Sarma, et al., *Cannabis Inflorescence for Medical Purposes: USP Considerations for Quality Attributes*, 83 J. NATURAL PRODUCTS 1334 (Apr. 13, 2020), https://pubs.acs.org/doi/10.1021/acs.jnatprod.9b01200.

[60] Wayne Labs, *Cannabis testing is an exact science – regulations are not*, FOOD ENGINEERING (June 24, 2019), https://www.foodengineeringmag.com/articles/98370-cannabis-testing-is-an-exact-science---regulations-are-not.

SHELF STABILITY, WATER ACTIVITY, AND MOISTURE CONTENT TESTING

As this industry moves toward legalization and recognition by the FDA, stability testing will become a more prevalent aspect of quality control and assurance systems. The objective of stability testing is to make data-driven determinations related to shelf stability for products. Companies currently operating under cGMP or intending to implement cGMP will have to address stability testing as a part of that standard. Shelf stability testing includes cannabinoid, terpene, and contaminant testing over time; water activity and moisture content testing; and sensory testing (e.g., color, taste, smell) over time. For example, flower might be tested for potency, cannabinoid profile, loss in drying, microbial growth, moisture content, and water activity, whereas concentrated products might involve similar tests but also include rancidity, oxidation, and package testing.

Stability testing addresses a variety of factors, including ingredient strength, microbial growth, water activity, oxidation, and packaging effectiveness. Two main types of stability evaluations are used for predicting shelf life. “Real-time” studies simulate the expected storage conditions over 12 to 24 months and run for the anticipated shelf life of the product, while “accelerated” studies use elevated temperatures and humidity to expedite the results over a shorter period (typically 6 months). It is recommended that stability testing be performed initially, then multiple times throughout the first 12 to 24 months to obtain data supporting the shelf life of the product, and then annually thereafter. Testing at least annually is considered minimal for compliance with cGMP.

Water activity testing measures the free, available water that is not bound to something else (e.g., sugars, salts, fats) and therefore can be used by microbes to grow; if there is enough unbound water in cannabis flower or a cannabis-derived product, then over time while sitting on a shelf, flower or product may become contaminated. On the other hand, moisture content is the measure of all water, whether free or bound, and is most important to test for in cannabis flower that is sold by weight, as a normalizing measure.

Expiration and “best by” dating have been frequent topics of conversation at the FDA for many years for different product categories. Expiration dates are generated from data provided by stability testing to inform consumers the last day a product is safe to consume. “Best by” dates, on the other hand, are used as a quality indicator. This date does not necessarily mean the product is no longer safe, but it may have lost its freshness, taste, aroma, or nutritional value. Another term that comes up often is the “use by” date, which applies only to perishable goods. Some states require such dates on labels for certain cannabis products. For example, Colorado currently requires expiration dates for edible cannabis products, nasal sprays, suppositories, and other alternative use products.[61] As of July 1, 2022, Colorado will also require expiration dates on cannabis vaporizer devices and inhalers.[62] NCLC recommends that federal regulators consider the use of these terms and their effectiveness in communicating stability and promoting accurate labeling in cannabis.

[61] COLO. CODE REGS. §§ 212-3-3-1015(B)(3)(c), 212-3-3-1015(B)(5)(c).

[62] COLO. CODE REGS. § 212-3-3-1010(C)(3)(k)(ii).

ASTM's D37 Committee published a Standard Guide for Stability Testing of Cannabis-Based Products to guide cannabis businesses on determining appropriate storage conditions and shelf life.[63] The industry can also draw guidance from other industries that have a long history of stability testing.[64] Table C details NCLC's minimum recommendations for a federally harmonized approach to shelf stability, water activity, and moisture content testing in consumer products containing cannabinoids based on these resources.

TABLE C. RECOMMENDATIONS FOR HARMONIZED STABILITY TESTING, WATER ACTIVITY, AND MOISTURE CONTENT TESTING REQUIREMENTS

Test	Flower, Pre-Rolls	Infused Pre-Rolls	Concentrates	Vaporizers	Edibles	Drinks	Tinctures	Topicals	Supplements, Pills, Capsules	Suppositories	Nasal Sprays, Inhalers
Stability – Cannabinoids	X	X	X	X	X	X	X	X	X	X	X
Stability – Terpenes	X	X	If terpenes are naturally present or added, perform tests; if no terpenes are added or present after extraction, testing is not recommended (e.g., distillate)		If terpenes are stated on the label						If terpenes are added and/or stated on the label
Stability – Microbials and Mycotoxins	X	X	X	X	X	X	X	X	X	X	X
Stability – Elemental Impurities				X							
Water Activity	X	X			X			X			
Moisture Content	X										

NCLC recommends cannabinoid concentration testing over time as part of stability testing in all cannabis-derived products, because cannabinoids are the active ingredients that are usually claimed on the label. Cannabinoids can degrade over time in some formulations based on interactions with other ingredients and/or under certain storage conditions. The group recommends that terpene testing be included in stability testing if terpenes are naturally present, added to the formulation, or claimed on the label. Since some extracting and manufacturing methods remove terpenes during processing, they are not present in the final product; therefore, the group does not feel that terpene testing should be required in these types of products.

[63] *ASTM D8309-21: Standard Guide for Stability Testing of Cannabis-Based Products*, ASTM INTERNATIONAL (Jul. 9, 2021), https://www.astm.org/d8309-21.html.

[64] *Stability Testing of New Drug Substances and Products Q1A(R2)*, ICH (Feb. 6, 2003), https://database.ich.org/sites/default/files/Q1A%28R2%29%20Guideline.pdf.

NCLC further recommends that microbial and mycotoxin testing be performed over time on all products as this type of contamination is most likely to occur if proper storage conditions are not maintained. Because of the vast variety of hardware choices (which are composed of metals) on the market, NCLC recommends that elemental impurity testing be performed over time specifically for vaporizer devices to determine if and when metals start leaching into cannabis extracts. The group recommends water activity testing in product types with higher risk of spoilage and moisture content testing for flower only because flower is sold by weight and the amount of water in flower can change drastically in different environments or under variable packaging conditions, thus altering the weight. Together, data from testing for cannabinoids, terpenes, contaminants, water activity, and moisture content can be used to defend an expiration or “use by” date.

TESTING INSTRUMENTATION, METHODS, AND PUBLISHED STANDARDS

Historically, many states have relied on other industries and standards groups to determine the appropriateness of certain methods and instruments for use in testing cannabis-derived products. While overlaying other industry standards can be a helpful starting place, several international and national organizations now exist that have established cannabis-specific working groups to address standardizing methodologies and instrumentation used in testing cannabis. These groups include the USP, which established an Expert Panel on Cannabis in 2016[65]; ASTM International's Committee D37 on Cannabis formed in 2017[66]; and AOAC International's Cannabis Analytical Science Program (CASP) formed in 2019.[67]

Within the last five years, these organizations have published a number of useful methods and guidelines that aim to align and standardize testing instrumentation and methods across the cannabis industry. There are now several published cannabis-specific standards. USP considerations for quality attributes in cannabis inflorescence provided scientifically validated analytical methods, data-based acceptance criteria and fit-for-purpose Reference Standards to define identity, composition and limits on contaminants.[68] AOAC International's CASP committee has published several Standard Method Performance Requirements (SMPRs) specific to cannabis testing, creating road maps that scientists and lab personnel can use to meet the minimum requirements for method development and validation.[69]

These national and international organizations, coupled with the growing number of scientific professionals engaged in cannabis compliance testing, have created a wealth of data that should be used to further define and refine allowable methods and testing standards across the industry. Table D below details the most common instrumentation used for different types of testing, which tests have SMPRs, and which tests have available consensus and public standard test methods for consumer products containing cannabinoids.

Because published standards are considered working documents that change over time, NCLC recommends that federal authorities incorporate available cannabis standards by reference to the extent possible and provide that the incorporation of the standards automatically makes effective the latest version of those standards.

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[65] *USP Expert Panel on Medical Cannabis*, USP (Aug. 30, 2016), https://www.uspnf.com/notices/usp-expert-panel-medical-cannabis#:~:text=USP%20invites%20qualified%20candidates%20to,cannabis%20used%20for%20medical%20purposes.

[66] *Committee D37 on Cannabis*, ASTM INTERNATIONAL, https://www.astm.org/get-involved/technical-committees/committee-d37 (last visited May 25, 2022).

[67] *Cannabis Analytical Science Program*, AOAC INTERNATIONAL, https://www.aoac.org/scientific-solutions/casp/ (last visited May 25, 2022).

[68] Nadakumara D. Sarma, et al., *Cannabis Inflorescence for Medical Purposes: USP Considerations for Quality Attributes*, 83 J. NATURAL PRODUCTS 1334 (Apr. 13, 2020), https://pubs.acs.org/doi/10.1021/acs.jnatprod.9b01200.

[69] *Resources, Uploads, & Archives*, AOAC INTERNATIONAL, HTTPS://WWW.AOAC.ORG/RESOURCES/?TOPIC=CANNABIS&TYPE=SMPRS&KEY= (last visited June 3, 2022).

TABLE D. INSTRUMENTATION, SMPRS, AND STANDARD METHODS FOR TESTING CANNABIS PRODUCTS

Test	Instrumentation	Available AOAC SMPRs for Validating Candidate Standard Methods for Cannabis	Available Standard Methods for Testing Cannabis Products
Microbials	qPCR, real-time PCR, culture-based plating, automated enumeration instruments, MALDI-TOF MS	SMPR for Viable Yeast and Mold Count Enumeration in Cannabis and Cannabis Products SMPR for Detection of Aspergillus in Cannabis and Cannabis Products SMPR for Detection of *Salmonella* species in Cannabis and Cannabis Products SMPR for Detection of Shiga Toxin–Producing *Escherichia coli* in Cannabis and Cannabis Products	Matrix Extensions of AOAC OMA 997.02 and AOAC OMA 2002.11 for Total Yeast and Mold in Cannabis USP general chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests USP general chapter <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms
Residual Solvents	GC-MS	SMPR for Identification and Quantitation of Selected Residual Solvents in Cannabis-Derived Materials	USP general chapter <467> Residual Solvents
Elemental Impurities (Metals)	ICP-MS	SMPR for Determination of Heavy Metals in a Variety of Cannabis and Cannabis-Derived Products	AOAC OMA 2021.03 - Heavy Metals in a Variety of Cannabis and Cannabis-Derived Products (Nov 2021) USP general chapter <233> Elemental Impurities−Procedures
Mycotoxins	LC-MS, LC-MS/MS, ELISA (confirmation method in addition to LC-MS)	SMPR for Quantitative Analysis of Mycotoxins in Cannabis Biomass and Cannabis-Derived Products SMPR for Mycotoxin Screening Technique in Cannabis Plant Material and Cannabis Derivatives	Aflatoxin tests according to the Method II or Method III in the USP general chapter <561> Articles of Botanical Origin: Test for Aflatoxins
Pesticides	LC-MS, LC-MS/MS, GC-MS, GC-MS/MS	SMPR for Identification and Quantitation of Selected Pesticide Residues in Dried Cannabis Materials	None identified.
Potency	HPLC, UPLC, LC-MS, LC-MS/MS, GC-MS, GC-MS/MS	SMPR for Quantitation of Cannabinoids in Edible Chocolate SMPR for Quantitation of Cannabinoids in Cannabis Concentrates SMPR for Quantitation of Cannabinoids in Dried Plant Materials	AOAC OMA 2018.10 - Cannabinoids in Dried Flowers and Oil AOAC OMA 2018.11 - Quantitation of Cannabinoids in Cannabis Dried Plant Materials, Concentrates, and Oils

Test	Instrumentation	Available AOAC SMPRs for Validating Candidate Standard Methods for Cannabis	Available Standard Methods for Testing Cannabis Products
		SMPR for Quantitation of Cannabinoids in Plant Materials of Hemp (Low THC Varieties Cannabis sp.)	
Water Activity	Resistive Electrolytic Hygrometers (REH), Capacitance Hygrometers, and Dew Point Hygrometers	None identified.	ASTM D8196-20 - Standard Practice for Determination of Water Activity (aw) in Cannabis Flower USP general chapter <922> Water Activity
Shelf Stability	For microbial and chemical contaminant testing, see respective methods listed above; for sensory testing: spectroscopy, organoleptic, olfactometry, and/or light scattering techniques.	None identified.	ASTM D8309-21 - Standard Guide for Stability Testing of Cannabis-Based Products
Terpenes	GC-MS, GC-MS/MS, GC-FID	None identified.	None identified.

Additional standards related to cannabis testing include, but are not limited to, the following:

- ASTM D8244-21a Standard Guide for Analytical Laboratory Operations Supporting the Cannabis/Hemp Industry
- ASTM D8282-19 Standard Practice for Laboratory Test Method Validation and Method Development
- ASTM D8334/D8334M-20 Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses
- ASTM D8222-21a Standard Guide for Establishing a Quality Management System (QMS) for Consumer Use of Cannabis/Hemp Products
- D8250-19 Standard Practice for Applying a Hazard Analysis Critical Control Points (HACCP) System for Cannabis Consumable Products

ACCREDITATION AND PROFICIENCY TESTING FOR LABS

Laboratory accreditations demonstrate the operational and technical competence of labs. The most common laboratory accreditation for testing labs globally is maintained by the International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) and is known as ISO/IEC 17025 accreditation.[70] The standard requires the lab to have a QMS and demonstrates that the lab is capable of providing reliable test results. To gain accreditation, labs must be audited regularly by a third party that is itself accredited to an ISO/IEC standard. While federal authorities do not require other testing labs to be ISO/IEC 17025 accredited (e.g., food labs), several states require this accreditation for cannabis labs. NCLC recommends that ISO/IEC 17025 accreditation be required for all cannabis labs upon federal legalization.

Proficiency testing (PT) is a critical means for testing laboratories to assess accuracy and reliability of test methods. PT can take various forms, from internally conducted blind sample studies to ISO-accredited programs conducted by third parties. Most ISO/IEC 17025 accrediting bodies, such as the American Association for Laboratory Accreditation (A2LA) and Perry Johnson Laboratory Accreditation, Inc. (PJLA), require accredited laboratories with multiple disciplines to participate in PT for every accredited test method, matrix, and analyte combination in cycles of every four years. PT requirements vary among state cannabis regulatory bodies, with some states requiring completion of one test method annually, and others requiring every approved matrix type (plant material, concentrates, and edibles) multiple times a year. The most common proficiency testing accreditation for proficiency test providers globally is known as ISO/IEC 17043 accreditation. To develop a standardized approach, NCLC recommends that a PT program be ISO/IEC 17043 accredited in order to meet federal standards.

PT programs can be acquired through standard-developing organizations such as ASTM International, government agencies such as NIST,[71] commercial entities such as Emerald Scientific,[72] or through agreements between laboratories and regulators in the same state, such as Colorado's potency PT program led by the Colorado Department of Public Health and Environment. Several programs for cannabis are under development, and availability is dependent on chemical class (e.g., cannabinoids, terpenes, pesticides, mycotoxins, heavy metals) and matrix materials (e.g., plant, oils, candies, beverages). At this time, suitable PT programs do not exist for many matrix materials or for all analytes recommended for regulatory testing.

The primary challenge for appropriate PT within the cannabis industry is the inability of PT providers to ship PT samples with Δ9-THC values greater than 0.3% across state lines. This has prevented providers from creating PT samples that accurately reflect what is being tested in the laboratory and limits the ability of testing laboratories to leverage the learnings that a proper PT program should allow. Federal legalization or

[70] *ISO/IEC 17025: Testing and Calibration Laboratories*, ISO, https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html (last visited May 25, 2022).

[71] *NIST Tools for Cannabis Laboratory Quality Assurance*, NIST (May 2019), https://www.nist.gov/programs-projects/nist-tools-cannabis-laboratory-quality-assurance.

[72] EMERALD SCIENTIFIC, https://emeraldscientific.com/ (last visited May 25, 2022).

descheduling will help remove this barrier. In the meantime, some states have had success in addressing this problem through an intrastate program where higher-THC products can be distributed to labs across the state, such as Oklahoma for their full panel of testing[73] and Colorado for potency testing only.[74]

NCLC recommends that state reference labs be involved in PT to help align analytical method performance abilities and expectations, and furthermore, that all cannabis laboratories participate in the same PT studies that are performed by the state reference laboratories.

It is the consensus of NCLC that the frequency of PT testing aligns with the PT requirements defined by accrediting bodies that approve other types of laboratories (e.g., food industry labs) to the ISO/IEC 17025 standard. We recommend that PT be required for any test that would (1) define cannabinoid content; (2) evaluate product safety; and/or (3) be used to verify ingredients claimed on the manufacturer's product label.

The following table, Table E, lists some of the available cannabis PT program providers.

TABLE E. EXAMPLES OF AVAILABLE CANNABIS PT PROGRAM PROVIDERS

PROVIDER	ENTITY TYPE	TESTS AVAILABLE
NIST CannaQAP[75]	Government	Currently includes testing for cannabinoids, toxic elements, and moisture in plant material. Statistics from the data are being used to create Certified Reference Material.
ASTM International[76]	International Standards Organization	Cannabinoids, terpenes, pesticides, residual solvents, elemental impurities, moisture content, and water activity in hemp flower.
AOAC International[77]	International Standards Organization	Hemp/cannabis pilot program for cannabinoids and pesticides targeted for April 2022. A second round of planned PTs are scheduled for Oct. 2022.
Absolute Standards, Inc.[78] (also provided through Emerald Scientific)	Commercial provider	Cannabinoids, terpenes, pesticides, residual solvents, elemental impurities, mycotoxins, water activity, and moisture content in hemp flower, hemp oil, and/or hemp edibles.
NSI Lab Solutions[79] (also provided through Emerald Scientific)	Commercial provider	Cannabinoids, terpenes, pesticides, residual solvents, elemental impurities, microbials, mycotoxins, water activity, moisture content, and foreign materials in hemp flower, hemp oil, and hemp edibles.
University of Kentucky[80]	Academic	Cannabinoids and terpenes in hemp flower and hemp oil.

[73] *Oklahoma Medical Marijuana Authority Seeing Benefits from Quality Assurance Lab Hired in August*, PUBLIC RADIO TULSA (Dec. 14, 2020), https://www.publicradiotulsa.org/local-regional/2020-12-14/oklahoma-medical-marijuana-authority-seeing-benefits-from-quality-assurance-lab-hired-in-august.

[74] *Proficiency Testing Information*, COLORADO DEPARTMENT OF REVENUE, https://sbg.colorado.gov/med/proficiency-testing-information (last visited May 25, 2022).

[75] *NIST Tools for Cannabis Laboratory Quality Assurance*, NIST (May 2019), https://www.nist.gov/programs-projects/nist-tools-cannabis-laboratory-quality-assurance.

[76] *Cannabis Proficiency Testing and Certification Programs*, ASTM INTERNATIONAL, https://www.astmcannabis.org/testing-certifications/ (last visited May 25, 2022).

[77] *Laboratory Proficiency Testing Program*, AOAC INTERNATIONAL, https://www.aoac.org/scientific-solutions/proficiency-testing/ (last visited May 25, 2022).

[78] ABSOLUTE STANDARDS INC, https://www.absolutestandards.com/ (last visited May 25, 2022).

[79] *Hemp Proficiency Tests*, NSI LAB SOLUTIONS (2022), https://www.nsilabsolutions.com/product-category/food/hemprm/hemppt/.

[80] *University of Kentucky Hemp Proficiency Testing Program*, UNIVERSITY OF KENTUCKY COLLEGE OF AGRICULTURE, FOOD AND ENVIRONMENT, https://www.rs.uky.edu/regulatory/hpt/ (last visited May 25, 2022).

BATCH SAMPLING AND SAMPLE SIZES

Sample collection is a critical step in the testing process. Collecting a representative sample, whether that consists of cannabis inflorescence or derivative products, is critical to ensuring that the final data produced reflects the entirety of the harvest and/or product batch.[81,82] The practice of representative sampling provides producers and consumers alike the confidence that a given cannabis product will contain the same levels of active compounds, such as Δ9-THC and CBD, throughout the batch. Representative sampling can also indicate the presence of contaminants within the batch, such as microbial pathogens like *Aspergillus spp.*, which in turn prevents that batch from being sold and posing a risk to public health.[83]

Although no consensus has yet been reached on the best practices for collecting a representative sample of cannabis, there is sample collection literature published for the food and feed industry[84] that outlines the sampling procedures necessary to create defensible measurement data.[85] This guidance outlines the following necessary requirements that a sampling plan should include: specifications of minimum mass/volume needed, minimum number of increments, selection of increment location, sample integrity requirements, sampling tools and equipment, and quality controls. While the industry continues to debate best practices for sampling various kinds of cannabis products, organizations such as ASTM are working to establish standards for post-harvest batch and final product testing.[86]

NCLC recommends the development and implementation of harmonized sampling plans and sample sizes. Because analytical data is only as good as the quality of the sample collection event, we recommend the samples are collected by an independent party (either the lab or a courier) to ensure proper sampling techniques are applied to obtain a sample that is truly representative of the production batch. A well-executed sampling strategy will result in representative data that accurately characterizes the product batch for potency, safety, and homogeneity.

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[81] Kim Watson, Representative and Random Cannabis Sampling, Sampler Quality Systems, and Demonstration of Competency in Sampler Protocols (254th ACS National Meeting & Exposition, Aug. 23, 2017), https://www.stone-env.com/assets/resources/211b376d13/Rep-and-Random-Cannabis-Sampler-QS-and-demo-Competency-in-sampler-Protocols_V2.pdf.

[82] *The Importance of Representative Sampling in Cannabis Analysis*, CANNABIS SCI. AND TECH. (Feb. 8, 2019), https://www.cannabissciencetech.com/view/importance-representative-sampling-cannabis-analysis.

[83] Kathy Hunt, *Representative Sampling of Cannabis*, ASTM INTERNATIONAL (Nov./Dec. 2020), https://sn.astm.org/?q=features/representative-sampling-cannabis-nd20.html.

[84] *GOODSamples*, AAFCO (2022), http://www.aafco.org/Publications/GOODSamples.

[85] *GOODTest Portions,* AAFCO (2022), http://www.aafco.org/Publications/GOODTestPortions.

[86] *Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses*, ASTM INTERNATIONAL (Dec. 1, 2020), https://www.astm.org/d8334_d8334m-20.html.

CONSIDERATIONS ON cGMP AND GAP

Given the evolving nature of the cannabis industry and its ever-expanding product lines, NCLC recommends the eventual implementation of cGMP for manufacturers of consumer products containing cannabinoids (e.g., edible manufacturers following food cGMP) and GAP for cannabis cultivators. The FDA enforces cGMP guidelines to ensure products are made in compliance with specified quality and regulatory standards for their intended use. Food and beverages, cosmetics, pharmaceutical products, dietary supplements, and medical devices are all types of products that must adhere to cGMP criteria. The guidelines include standards on product quality, manufacturing facilities, processes, documentation, training, procedures, distribution, and marketing. FDA registration by product type helps to determine the extent to which a company must comply, and companies may also choose to be certified to cGMP standards by an inspector and audited annually. It is important to note that facility guidelines incorporated in cGMP also address structural aspects of the facility (such as drain diameter, water pipe construction, and independent HVAC systems) that are costly for operators to update and may require an interim approach that prevents an unnecessary burden on legacy operators.

NCLC recommends eventually requiring the specific cGMP standards that address cannabis product quality, processes, documentation, and training procedures. These standards should address potency, testing panels, raw material validation, lot traceability, manufacturing procedures, quality control, quality assurance, product tracking, packaging, and employee training. In the interim, until cGMP is required in the cannabis industry, NCLC recommends implementing the harmonized approach to testing requirements detailed in this paper.

FEDERAL OVERSIGHT

As the cannabis industry develops, several critical areas will require some level of federal oversight. While many aspects of cannabis oversight will first require federal legalization, federal authorities can and should commence setting recommendations for testing standards now. Areas of primary concern when it comes to test standardization, some of which are addressed in this paper, include the following:

- *Testing panels*: which tests must be run, which compounds are included in an analysis, and when testing panels must be run based on product category or individual business risk assessments.
- *Reduced testing allowances*: circumstances under which there should be allowances for reduced testing.
- *Permissible levels and action limits*: what is the maximum allowable amount of contamination or tolerance to sell the product.
- *Sampling requirements*: how much sample is required to be tested, does sample size change based on batch size, how are samples to be taken (e.g., sample selection, compositing), how to interpret sample results, and setting sampling plan requirements or documentation requirements for sampling.
- *Frequency of testing*: how many batches need to be tested, and at what frequency.
- *Accreditation requirements for testing laboratories*: what standard for testing laboratories, such as ISO/IEC 17025, will be required to perform compliance testing.
- *Test result reporting requirements*: which parties should have access to test results, how will these results be reported, what requirements will exist around transparency and anonymity, and how will data be used to inform policymakers and the public.

This paper does not recommend permissible limits; however, these limits must be developed when defining a set of harmonized testing requirements at a federal level. Currently, state-mandated permissible limits of contaminants in cannabis products are mostly based on limits and safety data from other industries. For example, permissible limits for residual solvents are based on the USP general chapter <467>, which details solvent concentration limits in pharmaceuticals,[87] and permissible limits for pesticides are based on EPA limits in similar agricultural products.

Most often, limits in other industries are based on risk analysis,[88] toxicology data, and consumption data that comes from that specific industry. For instance, federal limits for microbial contaminants in dairy products come from data acquired in the dairy industry. To our knowledge, none of the current state-mandated limits for contaminants are based on risk and safety assessments from the cannabis sector. While it may make sense to pull data from other industries in certain instances (e.g., oral ingestion of a certain level of *Salmonella* will likely produce similar adverse health effects regardless of how it is ingested), other product types and action limits

[87] United States Pharmacopoeial Convention, *<467> Residual Solvents* in UNITED STATES PHARMACOPEIA – NATIONAL FORMULARY (2019), https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/generalChapter467Current.pdf.

[88] *Risk Analysis at FDA: Food Safety*, FDA (Feb. 2011), https://www.fda.gov/media/81256/download.

may not have a useful parallel. Inhalable products are one such example; due to their mode of consumption, assessing their risk and safety may be more difficult, and they may require different limits than those used in the food industry.

Federal encouragement of risk analyses, toxicology studies, and consumption surveys will play a critical role in informing policy decisions regarding permissible or action limits across the cannabis sector. The promulgation of cannabis testing regulations will likely fall under the authority of at least one federal agency and will require input from industry and existing cannabis regulators. Interstate commerce will be challenging without federally mandated testing requirements.

CONCLUSION

Federal classification of cannabis as a scheduled substance, coupled with a lack of federal guidance on state-legalized programs, has left many states to forge their own path in protecting consumer health and regulating cannabis products. Current variances in testing standards and a lack of consistent enforcement have created numerous state-based cannabis markets in which statements made on packaging/labels do not accurately reflect the products' ingredients within, leaving consumers wary of inconsistent experiences, unable to accurately dose, and vulnerable to biological and/or chemical contamination.

Federal legalization will present an opportunity to align testing requirements and create a more consistent, quality-focused approach that prioritizes the safety of patients and consumers. The recommendations made in this document present a cohesive approach to harmonizing testing standards intended to inform and protect consumers and to support a strong framework for a future federally legal system.

As we prepare for federal legalization and interstate commerce, it will be necessary for the cannabis industry to proactively develop testing standards that can be implemented across state lines. This work will help to avoid delays in the implementation of federal guidance and will allow for better oversight of consumer health and safety standards across the industry. Through collaborative efforts such as this, we aim to create a path forward to support regulators in avoiding the pitfalls associated with failing to proactively address the application of the dormant commerce clause in the cannabis sector. The future is now.

APPENDICES

APPENDIX A: ACRONYMS

ACRONYM	DEFINITION
A2LA	American Association for Laboratory Accreditation
ACIL	American Council of Independent Laboratories
AOAC International	Association of Official Analytical Collaboration
ASTM International	American Society for Testing and Materials
CASP	Cannabis Analytical Science Program
CBD	Cannabidiol
CBDA	Cannabidiolic Acid
CBG	Cannabigerol
CBGA	Cannabigerolic Acid
CBN	Cannabinol
CBNA	Cannabinolic Acid
cGMP	Current Good Manufacturing Practices
DCC	Dormant Commerce Clause
DHHS	Department of Health and Human Services
ELISA	Enzyme-Linked Immunosorbent Assay
EPA	Environmental Protection Agency
exo-THC	exo-Tetrahydrocannabinol
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAP	Good Agricultural Practices
GC-FID	Gas Chromatography/Flame Ionization Detector
GC-MS	Gas Chromatography–Mass Spectrometry
GRAS	Generally Recognized as Safe
HHC	Hexahydrocannabinol

ACRONYM	DEFINITION
HPLC	High Performance Liquid Chromatography
HVAC	Heating Ventilation and Air Conditioning
ICP	Inductively Coupled Plasma
ICP-MS	Inductively Coupled Plasma-Mass Spectrometry
ICP-OES	Inductively Coupled Plasma-Optical Emission Spectrometry
ILI	Independent Laboratories Institute
ISO/IEC	International Organization for Standardization/International Electrotechnical Commission
LC-MS	Liquid Chromatography–Mass Spectrometry
LOQ	Limit of Quantification
MALDI-TOF MS	Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry
NCLC	National Cannabis Laboratory Council
NIST	National Institute of Standards and Technology
NSI	National Science Institute
OMA	Official Methods of Analysis
PCR	Polymerase Chain Reaction
PJLA	Perry Johnson Laboratory Accreditation
PT	Proficiency Test(ing)
QMS	Quality Management System
qPCR	Quantitative Polymerase Chain Reaction
REH	Resistive Electrolytic Hygrometers
SMPR	Standard Method Performance Requirement
STEC	Shiga Toxin–Producing *Escherichia coli*
THC	Tetrahydrocannabinol
THCA	Tetrahydrocannabinolic Acid
TYAM	Total Yeast and Mold
UPLC	Ultra-Performance Liquid Chromatography
USP	United States Pharmacopeia

APPENDIX B: PESTICIDES

In 15 labs across 13 states, 80 pesticides have been detected in cannabis flower samples. The 29 pesticides shown in bold have been detected in cannabis flower samples in 3 or more states.

Abamectin	Clothianidin	Flupyradifuone	Prallethrin
Acephate	Coumaphos	Flupyradifurone	Propargite
Acequinocyl	Cyfluthrin	Hexythiazox	**Propiconazole**
Acetamiprid	Cyhalothrin lambda	**Imazalil**	Propoxur
Aldicarb	**Cypermethrin**	Imazapyr	**Pyrethrins**
Atrazine	**Daminozide (Alar)**	**Imidacloprid**	Pyridaben
Avermectin	**Diazinon**	Kresoximmethyl	Pyriproxyfen
Azadirachtin	**Dichlorvos (DDVP)**	**Malathion**	Spinetoram
Azoxystrobin	Dimethoate	**Metalaxyl**	**Spinosad**
Bifenazate	Dimethomorph	Methiocarb	**Spiromesifen**
Bifenthrin	Dinotefuran	Methomyl	**Spirotetramat**
Boscalid	Diuron	Methyl parathion	Spiroxamine
Captan	Ethoprop(hos)	**Myclobutanil**	**Tebuconazole**
Carbaryl	**Etofenprox**	Naled	Thiabendazole
Carbofuran	**Etoxazole**	Oxamyl	Thiacloprid
Chlorantraniliprole	Fenhexamid	Paclobutrazol	**Thiamethoxam**
Chlordane	Fenoxycarb	Parathionmethyl	Trifloxystrobin
Chlorfenapyr	Fenpyroximate	Pentachloronitrobenzene (PCNB)	
Chlormequat chloride	Fipronil	**Permethrins**	
Chlorpyrifos	Flonicamid	Phosmet	
Clofentezine	**Fludioxonil**	**Piperonyl butoxide**	

APPENDIX C: COMPARISON TO THE RECOMMENDATIONS OF OTHER GROUPS

TOPIC	NATIONAL CANNABIS LABORATORY COUNCIL (NCLC)	INDEPENDENT LABORATORIES INSTITUTE (ILI)	U.S. PHARMACOPEIA (USP)*
Cannabinoid Testing	**Recommend requiring for all products:** ∆9-THC, ∆9-THCA, ∆8-THC, CBD, CBDA, CBG, CBGA, CBN, CBNA **Others to consider in all products:** CBDV, CBDVA, THCV, THCVA, CBL, CBLA, CBC, CBCA, ∆10-THC, ∆9,11-THC, THCO acetate, HHC, and any other cannabinoid on the label **Cannabinoid concentration calculation:** Total THC = THC + (0.877 x THCA) Total CBD = CBD + (0.877 x CBDA)	**Recommend requiring for all products:** ∆9-THC, ∆9-THCA, CBD, CBDA, CBG, CBGA, CBN, ∆8-THC (or any other isomers of THC, as needed) **Others to consider in all products:** CBNA, CBDV, CBDVA, THCV, THCVA, CBL, CBLA, CBC, CBCA, CBT, ∆10-THC, 6a,10a -THC, and any other cannabinoid on the label **Cannabinoid concentration calculation:** Total [cannabinoid] concentration (mg/g) = ([cannabinoid] acidic form concentration (mg/g) x 0.877) + ([cannabinoid] concentration (mg/g) + ...) For example, total THC = THC + (0.877 x THCA)	**Recommend requiring for flower:** ∆9-THC, ∆9-THCA, CBD, CBDA, CBG, CBGA, CBN, CBDV, CBDVA, THCV, THCVA, CBC, ∆8-THC **Cannabinoid concentration calculation:** Total THC = THC + (0.877 x THCA) Total CBD = CBD + (0.877 x CBDA)
Terpene Testing	**Recommend requiring for flower and pre-rolls:** • α-pinene • β-myrcene • β-caryophyllene • limonene • terpinolene **For all products: All other terpenes required to be tested for if individual terpene(s) or the total terpene content is on the label**	**Recommend requiring (product type not specified):** • α-pinene • β-myrcene • β-caryophyllene • limonene • terpinolene • β-pinene • linalool • humulene • caryophyllene oxide • α-bisabolol **Others to be considered:** • ocimene isomers • cis- & trans-nerolidol • delta-3-carene • camphene • p-cymene • guaiol • geraniol • alpha-terpinene • gamma-terpinene • terpineol isomers • eucalyptol • borneol alpha and beta farnesene	**Recommend requiring for flower:** • α-pinene • β-myrcene • β-caryophyllene • limonene • terpinolene

TOPIC	NATIONAL CANNABIS LABORATORY COUNCIL (NCLC)	INDEPENDENT LABORATORIES INSTITUTE (ILI)	U.S. PHARMACOPEIA (USP)*
Microbial Testing	**Recommend requiring for all products:** • TYAM • STEC • *Salmonella* • *Aspergillus flavus, A. fumigatus, A. niger,* and *A. terreus* • Total Coliform **Recommend requiring for specialized products such as suppositories, nasal sprays, and inhalers:** • Total Aerobic • Total Gram-Negative Bacteria • *C. albicans* • *S. aureus* • *P. aeruginosa*	**Recommend requiring for all products:** • TYAM • STEC • *Salmonella* • Total Aerobic • Total Gram-Negative Bacteria • *Aspergillus flavus, A. fumigatus, A. niger,* and *A. terreus* • Total Coliform	**Recommend requiring for flower:** • TYAM • STEC • *Salmonella* • Total Aerobic • Total Gram-Negative Bacteria Mentions *Aspergillus* testing but notes there is no compendial method available currently
Mycotoxin Testing	**Recommend requiring in all products:** • Aflatoxins B1, B2, G1, G2 • Ochratoxin A	**Recommend requiring in all products:** • Aflatoxins B1, B2, G1, G2 • Ochratoxin A	**Recommend requiring to conform to state requirements**, plus aflatoxin testing according to Method II or Method III in USP <561>
Solvent Testing	**Classifies solvents per USP <467>** **Recommend requiring in pre-rolls infused with solvent-based concentrates, solvent-based concentrates, vaporizers, nasal sprays, and inhalers:** • Class I solvents • Class II solvents **Recommend requiring in pre-rolls infused with solvent-based concentrates, solvent-based concentrates, vaporizers, nasal sprays, and inhalers:** • Class III solvents if intentionally added during extracting or manufacturing • Any other solvents if intentionally added during extracting or manufacturing	**Classifies solvents per USP <467>** **Recommend requiring in finished and unfinished cannabis products:** • Class I solvents • Class II solvents • Class III solvents	No recommendations for solvents because the paper only addresses flower

Standardizing Cannabis Lab Testing Nationally

TOPIC	NATIONAL CANNABIS LABORATORY COUNCIL (NCLC)	INDEPENDENT LABORATORIES INSTITUTE (ILI)	U.S. PHARMACOPEIA (USP)*
Pesticide Testing	No recommended panel, but rather provides risk-based data for federal agencies and recommends using it to create a national panel with action limits based on human health assessments and toxicology data specific to the intended consumption method	Recommends considering AOAC SMPR 2018.011's list of 104 pesticides that includes Canada's list (96 pesticides) for cannabis and cannabis-derived products	Requires conforming to the state's requirements and recommends considering other pesticides "if there is reason to believe they may be present in a botanical product"
Elemental Impurity Testing	**Recommend requiring for inhaled products:** • Arsenic • Cadmium • Chromium • Copper • Lead • Mercury • Nickel **Additional compounds to be considered in inhaled products if used in manufacturing or part of a device that can leach into extracts:** • Antimony • Barium • Cobalt • Gold • Iridium • Lithium • Molybdenum • Osmium • Palladium • Platinum • Rhodium • Ruthenium • Selenium • Silver • Thallium • Tin • Vanadium **Recommend requiring for other products:** • Arsenic • Cadmium • Mercury • Lead • Nickel	**Recommend requiring for all products:** • Arsenic • Cadmium • Chromium • Copper • Lead • Mercury • Nickel **Additional compounds to be considered:** • Antimony • Barium • Chromium • Copper • Nickel • Silver • Selenium • Zinc	**Recommend requiring for flower:** • Arsenic • Cadmium • Mercury • Lead Per USP <232>, "when additional elemental impurities are known to be present, have been added, or have the potential for introduction, assurance with the specified levels is required"

TOPIC	NATIONAL CANNABIS LABORATORY COUNCIL (NCLC)	INDEPENDENT LABORATORIES INSTITUTE (ILI)	U.S. PHARMACOPEIA (USP)*
Elemental Impurity Testing (Continued)	**Additional compounds to be considered in other products if used in manufacturing the product:** • Antimony • Barium • Chromium • Cobalt • Copper • Gold • Iridium • Lithium • Molybdenum • Osmium • Palladium • Platinum • Rhodium • Ruthenium • Selenium • Silver • Thallium • Tin • Vanadium		
Other Testing	**Shelf stability testing required:** • Cannabinoid testing over time for all products • Terpene testing over time for flower and pre-rolls, concentrates, and vaporizers if terpenes are naturally present or added, and for other products if they are stated on the label • Microbial testing over time for all products • Elemental impurities testing over time for vaporizers **Water activity testing required** for flower, pre-rolls, edibles, and topicals **Moisture content testing required** for flower and pre-rolls	**Water activity testing required** for all products **Moisture content testing required** for flower only	**Water activity testing recommended** for flower **Moisture content testing is not recommended** for flower because water activity testing is recommended **Control for foreign organic matter recommended** for flower to exclude any other plant parts or matter except for inflorescence, such as seeds and stems **Total ash and acid-insoluble ash testing recommended** for flower

Standardizing Cannabis Lab Testing Nationally

TOPIC	NATIONAL CANNABIS LABORATORY COUNCIL (NCLC)	INDEPENDENT LABORATORIES INSTITUTE (ILI)	U.S. PHARMACOPEIA (USP)*
Other Topics Discussed	• Need for public quality standards and harmonized laboratory testing protocols • Recommended technologies, methodologies, and standards • Need for laboratory accreditation and proficiency testing • Need for quality control and consistent manufacturing practices • cGMP and GAP for cultivators and manufactures • Federal oversight, interstate commerce, and dormant commerce clause • Need for data collection, human health assessments, and toxicology studies for action limits specific to cannabis • List of PT providers • Batch sampling and sample sizes	• Need for public quality standards and harmonized laboratory testing protocols • Recommended technologies, methodologies, and standards • Need for laboratory accreditation and proficiency testing • Laboratory QMS components (e.g., personnel training, document control, nonconformances) • Analytical testing batch QC requirements and criteria for each test • Calibration criteria for each test • Action limits for some analytes • Definitions and terminology included	• Need for public quality standards and harmonized laboratory testing protocols • Recommended technologies, methodologies, and standards • Need for quality control and consistent manufacturing practices • Action limits for some analytes • Need for standardized nomenclature and definitions • Cannabis chemotypes • Naming in laws and regulations • Packaging and storage • Labeling • Adulteration with synthetic cannabinoids

*Only addresses cannabis flower and no other products.

CONTRIBUTORS

ABOUT NCLC

The National Cannabis Laboratory Council (NCLC) was formed in 2021 by the law firm of Perkins Coie LLP and numerous lab scientists and operators from around the country. The coalition's mission is to establish and promote science-based national lab testing standards for cannabis products. The establishment of national standards will create a pathway for interstate commerce of cannabis products and resolve the issues associated with varying state-based testing requirements. Promulgating national standards will further protect public health by ensuring that testing for certain pesticides, elemental impurities, and harmful additives will be consistent throughout the United States. Please visit www.perkinscoie.com/en/news-insights/nclcouncil.html to learn more.

AUTHORS

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Managing Director, Rm3 Labs

Alena Rodriguez is the managing director at Rm3 Labs, an analytical cannabis testing facility in Colorado. She has an M.S. in biomedical sciences and a B.S. in biology from Florida Atlantic University. Before entering the cannabis industry, Alena worked in molecular biology, analytical chemistry, and neuroscience laboratories. She joined Rm3 Labs in January 2016 and spent her first two years testing microbial samples and developing contaminant testing methods. She has also served as the lab's quality manager and led the lab's efforts to become ISO 17025 accredited.

In her current position, she manages the lab's daily operations and works with governmental agencies and stakeholders to advance cannabis regulations. Alena is the recording secretary of the Laboratory Subcommittee of ASTM International's Committee D37 on Cannabis and the Process Validation Task Group leader of the Marijuana Enforcement Division and Colorado Department of Public Health and Environment's Marijuana Science & Policy Work Group. She is also a member of AOAC CASP's Microbiology Working Group and a current member and former chair of the National Cannabis Industry Association's Scientific Advisory Committee.

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Elisabeth Berry
Chief Operating Officer, PSI Labs

PSI LABS

Elisabeth Berry is the chief operating officer of PSI Labs, a multi-state cannabis testing laboratory. As COO, Elisabeth oversees the lab's finance, human resources, compliance, and operations teams with a focus on guiding the company's strategic planning and expansion. Prior to joining PSI Labs, Elisabeth led operations and growth initiatives across diverse industries (including venture capital, food and beverage, and tech and healthcare M&A operations), supporting businesses and organizations to scale strategically and sustainably. Elisabeth's passion for early-stage companies has led to participation on a number of investment review committees as well as board positions across private and not-for-profit organizations, including her current board role with the Autism Alliance of Michigan.

Elisabeth holds an MBA from George Washington University, a graduate certificate in public health from the University of Michigan's School of Public Health, and a bachelor's degree in economics from the University of Michigan.

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PSI LABS

Frank Barretta is the director of quality & compliance for PSI Labs, a multi-state cannabis testing laboratory. In this role, Frank oversees the regulatory and accreditory alignment of PSI Labs' internal policies. Frank is an active member in both the AOAC CASP and ASTM D37 cannabis-specific standardization workgroups. Prior to joining PSI Labs, Frank served as the quality assurance officer for the Michigan Department of Agriculture and Rural Development, specifically facilitating USDA Pesticide Data Program and EPA FIFRA Program policy. Frank received his B.A. in biochemistry and biology from Olivet College and his M.S. in genetics from Clemson University.

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Arizona | California | Colorado | Florida | Massachusetts | Nevada | New York | Oregon | Tennessee

James Horvath co-founded Kaycha Laboratories and is part of the company's executive office. He shares responsibility for oversight of day-to-day operations of the business and his primary areas of focus are business development, compliance/accreditation, quality control, technology, and legal.

Prior to Kaycha, Mr. Horvath co-founded Revelex, one of the largest travel technology companies in the world, conducting over $4 billion in annual travel sales. The company provides technology to American Express, AAA, Wells Fargo, and numerous other Fortune 100 companies.

Prior to that, he held leadership positions as a technology-focused executive at Quest Technologies and Dollar Thrifty Automotive. Mr. Horvath holds the following designations: CGEIT, CISA, CISSP, PMP, SCJP, and CSOX. He also served in the United States Air Force.

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Stephen Goldman joined PhytaTech (the predecessor company to Kaycha Labs Colorado) in 2015. His primary areas of focus are Colorado lab operations, research and development, new test development, and nationwide standardization.

Prior to joining Kaycha, Mr. Goldman served as an analytical chemist at the CLIA- and CAP-certified Forensic Laboratories; was a chemist for Novartis (Sandoz), Kemin Industries, and Genentech; and served as a contract chemist. In those capacities, he researched biocatalyst production, new chemistry entities, nutraceutical development, antibody conjugate linkers, technical transfers, quality control, analytical method development, and method creation and validation.

Mr. Goldman is a member of the American Institute of Chemical Engineers, American Association of Pharmaceutical Scientists, and the American Chemical Society, Cannabis Chemistry Subdivision.

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Concetta DiRusso, Ph.D.
President and Chief Executive Officer, Kennebec Analytical Services

Dr. Concetta DiRusso is the president and CEO of Kennebec Analytical Services, LLC (KAS). Located in Lincoln, it is Nebraska's only commercial laboratory dedicated to providing a range of testing services for the hemp cannabis industry. Dr. DiRusso is also the Emerita George Holmes University Professor of Biochemistry at the University of Nebraska, Lincoln, a fellow of the American Association for the Advancement of Science, and a Jefferson Science Fellow of the National Academy of Sciences. She has published over 100 research articles and holds five patents. In 2020, Dr. DiRusso started Kennebec Analytical Services to support the burgeoning hemp industry in the Midwest. KAS works directly with farmers and hemp product producers to assess the chemical composition of their plants and products for compounds ranging from valuable cannabinoids and terpenes to contaminants such as pesticides and mycotoxins. KAS is the approved testing facility of the Nebraska State Department of Agriculture and the USDA for the 2022 harvest.

Kristofer Marsh, Ph.D.
Chief Scientific Officer, Green Scientific Labs

Dr. Kristofer Marsh serves as chief scientific officer at Green Scientific Labs, a commercial cannabis and hemp testing laboratory with locations in Florida and Arizona. Since 2017, Dr. Marsh has worked in the cannabis testing industry in roles of increasing responsibility. He has presented at numerous cannabis industry conferences on topics ranging from infused beverages to delta-8 THC and is also a voting member of ASTM Committee D37 on Cannabis. He has also advised policymakers across the United States on state cannabis testing regulations. Dr. Marsh received his B.S. in chemistry from Towson University and his Ph.D. in materials chemistry from UCLA.

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Craig Draper, Ph.D.

Dr. Craig Draper is vice president of business development for Smithers, where he focuses on expanding services to meet the needs of existing and emerging markets. Smithers provides cannabis and hemp testing in a growing number of states with a focus on providing leading scientific expertise and state-of-the-art instrumentation to deliver trustworthy data, open access to experts, and rapid results. Dr. Draper received his B.Sc. (Hons) in microbiology from Sheffield University, UK, and his Ph.D. in microbial genetics from the University of Edinburgh, UK, followed by post-doctoral studies at UCLA.

Liz Geisleman
CEO, Rocky Mountain Reagents

Liz Geisleman was named chief executive officer for Rocky Mountain Reagents (RMR) in 2022 after 24 years of developing and managing all aspects of the growing business. RMR was among the first to help support the nascent cannabis industry with legalization in Colorado over a decade ago. RMR specializes in high-grade chemicals for industry clusters such as aerospace, healthcare, biotech, forensics, cannabis extraction, and testing. RMR has been honored as a Top 100 Woman-Owned Business, a Top 250 Privately Owned Company, a Colorado Company to Watch, and Woman/Minority Business of the Year.

After spending 12 years in politics and 20 years in specialty chemical sales, Liz worked to become intimately involved in shaping, advising, and educating within the cannabis industry to mirror what traditional food and dietary markets might require. In the past few years, she has participated as a stakeholder for standardized testing and manufacturing protocols on the Colorado Hemp Advancement Management Plan initiative set by Governor Polis, the Manufacturing Committee with the National Cannabis Industry Association (NCIA), and the National Cannabis Laboratory Council. Liz currently serves on the NCIA Board of Directors, which focuses on national cannabis policies, and locally with Marijuana Industry Group and Colorado Hemp Industries policy committees.

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Andrew Kline is senior counsel in Perkins Coie's Denver office. He advises companies involved in all aspects of cannabis law and policy, regulatory compliance, civil litigation, and investigations. He brings a rare combination of public policy, cannabis, and prosecutorial experience to the firm, following decades of service in the highest levels of government and in the private and nonprofit sectors. Andrew also has a deep and celebrated background in coalition creation and management, and he served as public policy director for the National Cannabis Industry Association. Drawing on his nearly 15 years of experience as a federal prosecutor, as well as public service working as policy advisor to then-Vice President Joe Biden and counsel to then-Senator Biden, Andrew represents clients in some of the most sensitive areas of law and policy.

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Tommy Tobin
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Tommy Tobin is an associate in Perkins Coie's Seattle office, where he focuses on complex commercial litigation and class action matters involving statutory, constitutional, and regulatory issues in a range of industries, including food and beverage and cannabis. He recently edited the American Bar Association's book *Food Law: A Practical Guide* and serves as a lecturer at UCLA Law School.

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As the National Cannabis Laboratory Council has been working to produce the harmonized approach to cannabis testing described herein, many others have been addressing similar issues from different perspectives. We would like to acknowledge the important work of organizations such as the American Council of Independent Laboratories (ACIL) and the United States Pharmacopeia (USP) in elevating these topics and publishing analysis that we believe to be aligned with the goals of the scientific community at large and NCLC in refining the field of cannabis laboratory testing.

The ACIL Independent Laboratories Institute (ILI) has recently published, for comment, its *Guide to a Harmonized National Cannabis Laboratory Accreditation Program*, which dives deeper into the topic of laboratory accreditation, such as ISO 17025:2017 and ALACC, with additional attention to detection and quantitation limits across testing panels. In 2020, USP's Cannabis Expert Panel published toxicological considerations and a basis for establishing quality specifications for medical cannabis to protect public health and facilitate scientific research. These organizations along with others referenced within this document, such as AOAC International's CASP and ASTM International's D37 Committee on Cannabis, have accomplished a great deal in furthering the topic of cannabis testing and safety standards, and continue to play an important role in the future of this industry.

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