REGULATING PATIENT HEALTH

AN ANALYSIS OF DISPARITIES IN STATE CANNABIS TESTING PROGRAMS

JULY 2023

Americans for Safe Access
Advancing Legal Medical Cannabis Therapeutics

THE MISSION OF AMERICANS FOR SAFE ACCESS (ASA) IS TO ENSURE SAFE AND LEGAL ACCESS TO CANNABIS FOR THERAPEUTIC USE AND RESEARCH.

WITH OVER 150,000 ACTIVE SUPPORTERS IN ALL 50 STATES, ASA IS THE LARGEST NATIONAL MEMBER-BASED ORGANIZATION OF PATIENTS, MEDICAL PROFESSIONALS, SCIENTISTS, AND CONCERNED CITIZENS WORKING TO OVERCOME POLITICAL, SOCIAL, AND LEGAL BARRIERS TO IMPROVE ACCESS TO MEDICAL CANNABIS FOR PATIENTS AND RESEARCHERS THROUGH LEGISLATION, EDUCATION, LITIGATION, GRASSROOTS EMPOWERMENT, ADVOCACY AND SERVICES FOR PATIENTS, GOVERNMENTS, MEDICAL PROFESSIONALS, AND MEDICAL CANNABIS PROVIDERS.

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For science. For action. For health.

As states have legalized cannabis for medical use, patient safety has been at the forefront of many public health discussions. As we navigate this complex landscape, we must emphasize the importance of developing comprehensive regulations and monitoring production for potential contaminants associated with cannabis use.

The recognition of cannabis's therapeutic potential has led to increased use in treating various medical conditions, including chronic pain, epilepsy and multiple sclerosis. With more individuals relying on cannabis for their well-being, we need to ensure all patients have access to safe and reliable products. Regulating the production, distribution and consumption of cannabis is essential for safeguarding public health and ensuring patient safety.

In particular, testing cannabis for contaminants promotes safe consumption by identifying and eliminating potential health hazards. By implementing stringent testing protocols, states can ensure that cannabis products meet quality standards and are free from harmful substances, properly labeled and safe for consumption by patients. This proactive approach aligns with the principles of public health and prevention, prioritizing the well-being of those who rely on cannabis for their medical needs.

Comprehensive testing not only protects patients but also helps establish a foundation for evidence-based regulations and guidelines. Accurate data on the prevalence and impact of contaminants can inform policymakers, healthcare professionals, regulators and consumers, as they formulate effective strategies for risk mitigation, education and harm reduction. This information also enhances public awareness and contributes to a more informed and responsible approach to cannabis use.

As with any agricultural product, cannabis plants are susceptible to the accumulation of pesticides, heavy metals, and microbial pathogens during cultivation and processing. Unregulated and untested cannabis products may contain these harmful contaminants, jeopardizing the health and well-being of patients.

By examining the importance of testing cannabis for contaminants through the lens of patient safety, public health and prevention, this report underscores the need for robust testing frameworks and regulatory mechanisms. Currently, testing of cannabis products is inconsistent between states, with differences in the compounds and species that products are tested for and the limits for those substances, as well as varying methodologies and reporting units. This lack of regularity creates problems for laboratories and multi-state operators, which are required to adhere to different standards depending on where they are operating.

Since its inception, Americans for Safe Access has been at the forefront of championing policies that improve access to medical cannabis for patients and researchers through legislation, education, litigation, research, grassroots empowerment, advocacy and services for patients, governments, medical professionals and medical cannabis providers. This report is in lockstep with the organization's previous efforts to center the patient voice and it serves as a catalyst to establish a consistent approach to test cannabis for medical consumption.

Mighty Fine

Interim Associate Executive Director
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INTRODUCTION

The legalization of cannabis for medical purposes has gained significant momentum throughout the United States, offering patients a potential alternative for managing their health conditions. Today there are over 6 million registered medical patients across the country that depend on state medical cannabis programs for access to their medicine. However, ensuring the safety and quality of cannabis products remains a paramount concern in this rapidly evolving landscape. Robust regulation of cannabis testing programs plays a crucial role in protecting patient health by identifying potential contaminants and providing accurate labeling of cannabis products..

This report meticulously examines the existing disparities in cannabis testing programs across various states as they relate to other regulated products, with a particular focus on their impact on patient well-being. Developed by Americans for Safe Access, a leading organization dedicated to promoting safe and legal access to cannabis for therapeutic use, this report aims to shed light on the pressing issues surrounding cannabis testing and advocate for enhanced regulations to safeguard patient health.

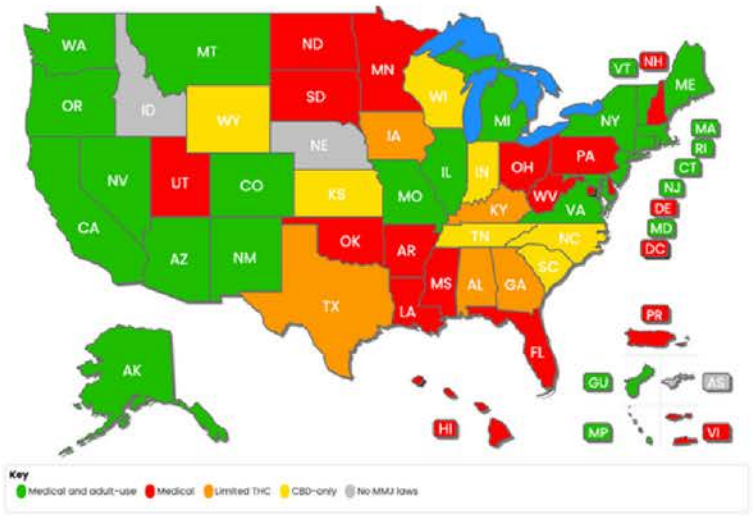


FIGURE 1: AMERICANS FOR SAFE ACCESS STATE LAW HUB

As of June 2023, 42 states have active medical and/or adult-use cannabis programs, all operating outside and in conflict with federal laws and regulations. The first medical cannabis law was passed in 1996, but it wasn't until 2014 that Colorado implemented requirements for the testing of adult-use products for potency and homogeneity, establishing state-mandated quality control standards. These regulations built on the release of the American Herbal Product Association's (AHPA) Guidelines for Regulators and the launch of Americans for Safe Access' (ASA) Patient Focused Certification (PFC) program. With limited federal guidance, states took the initiative to implement product safety standards to protect patients and consumers and prevent contaminated products from entering the market. While most states have now adopted testing programs, significant disparities persist, varying from state to state and even from test to test.

ASA's 2022 State of the States Report: An Analysis of Medical Cannabis Access in the United States (www.safeaccessnow.org/sos) confirmed these disparities, and highlighted the need for improvements, with states averaging a score of 44% in the Consumer Protection and Product Safety category, making it one of the lowest scoring categories in the report. Patient feedback responses, reported through surveys conducted as part of the report, consistently emphasized the importance of the need for continuous improvements to product safety standards, including testing programs, throughout the cannabis supply chain.

Testing programs serve two critical roles in the cannabis marketplace. First, like other agricultural commodities, product safety standards should encompass guidelines from seed to consumption, and testing programs act as oversight tools to ensure the enforcement of these protocols, alongside inspections and certifications. Second, unique to pharmaceutical agriculture and especially relevant to cannabis, testing programs inform consumers about the cannabinoid and terpene content in products. Medical cannabis, as a highly personalized medication, relies on testing programs to ensure freedom from contaminants, pesticides, and provide accurate dosage information.

Currently, testing programs in different states exhibit significant variations in terms of the types of tests required, contaminants tested for, acceptable levels of contaminants in cannabis products, and procedures for handling failed tests. This creates a concerning disparity in the quality and safety of cannabis medicine available to patients and consumers. For individuals with compromised immune systems, pediatric patients, or elderly patients on multiple medications, the presence or absence of contaminants can have a profound impact on their well-being.

Furthermore, many patients and consumers are unaware that their cannabis may not undergo testing for numerous contaminants highlighted in this report. In some cases, like in the District of Columbia (D.C.), the absence of a licensed testing facility has left cultivators to have to test their own products. Limited self-testing, often focusing only on potency, THC, and CBD, falls short of comprehensive testing for heavy metals, mold, pesticides, and terpenes.

Maine, a state where most patients get their medicine through caregivers, encourages, yet does not require the testing of medical cannabis, only recreational. In 2019, Maine passed only voluntary medical cannabis testing with no legislatively designated standards, analytes for testing, or a system to track cannabis products that would ensure the integrity of the testing system but only after complaints about sicknesses suffered by medical cannabis patients. Testing of products used by those patients found harmful solvents like naphtha, used in paint thinner, and rubbing alcohol, as well as an array of pesticides, molds and harmful bacteria.

Additionally, there is a lack of mandatory educational programs to raise awareness about contaminants and related health concerns. Only eight states currently require businesses to provide a Certificate of Analysis (CoA) to consumers, enabling informed purchasing decisions based on concentrations of major cannabinoids and terpenes, microbial and fungal contaminants, heavy metal levels, and measurements of pesticide and solvent residues.

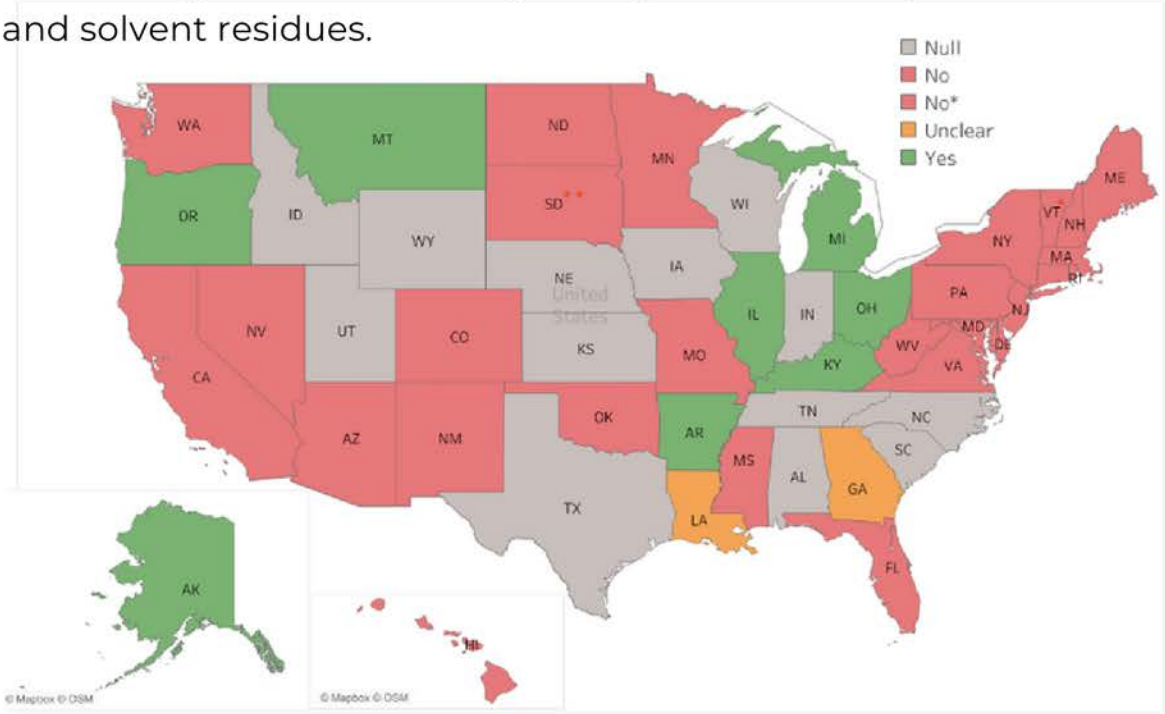


FIGURE 2: STATES THAT REQUIRE LAB NAME ON CANNABIS LABELS.

* No, but requires website / QR code

** No, but there is only 1 lab

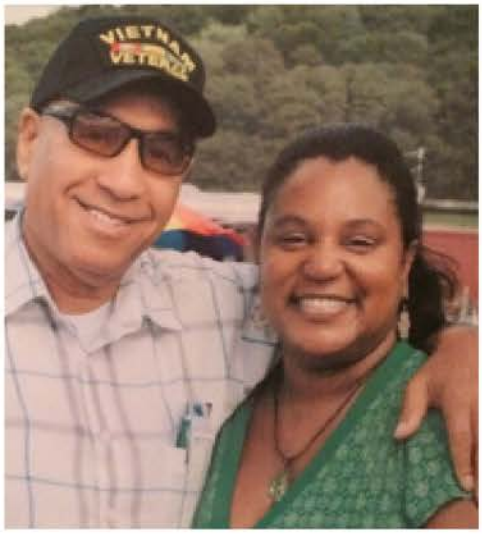
This report delves into potential health outcomes associated with contaminants commonly found in cannabis products. It provides a comprehensive summary of testing requirements across different jurisdictions and explores essential criteria for testing laboratories. Specific areas of testing, including potency and homogeneity, terpenes, pesticides, residual solvents, heavy metals, microbiological contaminants, and aflatoxins, are thoroughly examined to identify gaps and inconsistencies in current regulations, offering a foundation for more effective and uniform testing practices.

State and federal policymakers have the power to shape and refine the regulatory framework surrounding cannabis testing. By carefully reviewing the findings and recommendations presented in this report, policymakers can actively contribute to the advancement of cannabis testing programs that prioritize patient health and ensure the availability of safe, reliable, and effective cannabis products for those in need. It is our hope that state legislators will not only take action to improve their product safety and testing programs including consumer education but will also join Americans for Safe Access in our call to Congress to create a National Office of Medical Cannabis and Cannabinoid Control (OMCCC) to work with states to improve testing programs for the health of patients.

We invite you to explore this comprehensive analysis, consider its implications, and champion the cause of patient health by advocating for robust and uniform cannabis testing regulations. It is time to foster an environment where patients in every state, can confidently access cannabis products that meet the highest standards of safety and quality.

LIVING WITH CANNABIS AS A MEDICINE

A medical cannabis patient is s a person living with a medical condition or experiencing symptoms for which cannabis or a cannabinoid-based therapeutic is the only treatment option, a more suitable option, or works as an adjunct treatment including side-effect mitigation to other available care options. There are over 6 million registered medical cannabis patients across the United States that depend on state medical cannabis programs for access to their medicine.



Living with cannabis as a medicine means that patients require their medication to control the symptoms of their diseases or conditions, enabling them to carry out essential life activities such as work, school, and childcare. Daily use of cannabis is often required to maintain symptom relief and overall well-being, and any interruption or inconsistency in their medication can have significant consequences for their treatment success and quality of life.

Unlike other medications that come in standardized formulations, cannabis is highly individualized in terms of its therapeutic effects. Patients rely on accurate and detailed labels to ensure they are obtaining the specific formulations and potencies that work best for their medical conditions. Medical cannabis patients and their healthcare providers depend on proper labeling of cannabis products to determine the best treatment outcomes.

OVER 6 MILLION REGISTERED PATIENTS

The following conditions are approved to be treated with medical cannabis:

Agitation of Alzheimer's * Admittance into hospice care * Alzheimer's disease (including agitation of) * Amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease) * Anorexia * Anxiety disorders * Any other condition that is severe and resistant to conventional medicine * Arnold-Chiari malformation * Arthritis * Asthma * Attention deficit disorder / attention-deficit/hyperactivity disorder (ADD/ADHD) * Autism * Bipolar disorder * Bulimia * Cachexia or wasting syndrome * Chronic Pain * Cancer * Causalgia (complex regional pain syndrome (CRPS) Type 2) * Cerebral palsy * Chemotherapy treatment * Chronic autoimmune inflammatory disorders (including rheumatoid arthritis) * Chronic inflammatory demyelinating polyneuropathy (CIDP) * Chronic vocal or motor tic disorder * Chronic pancreatitis * Chronic renal failure requiring hemodialysis * Chronic traumatic encephalopathy (CTE) * Crohn's disease * Complex regional pain syndrome (CRPS) / reflex sympathetic dystrophy (RSD) * Corticobasal degeneration * Cystic fibrosis * Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity * Decompensated cirrhosis * Degenerative or pervasive neurological condition * Dementia * Depression * Diabete s * Dyskinetic and spastic movement disorders * Dystonia * Ehlers-Danlos syndrome * Elevated intraocular pressure * Endometriosis * Epidermolysis bullosa * Fibromyalgia * Fibrous dysplasia * Glaucoma * Hepatitis C * HIV/AIDS * Huntington's disease * Hydrocephalus * Hydromyelia * Immune-mediated inflammatory diseases * Inclusion body myositis * Inflammatory bowel disease (IBD) * Insomnia * Interstitial cystitis / bladder pain syndrome * Intractable appetite loss * Intractable cramping * Intractable headache syndromes, including intractable migraines * Intractable nausea or vomiting * Intractable skeletal muscular spasticity * Intractable Neuropathic Pain * Irritable bowel syndrome (IBS) * Irreversible spinal cord injury with objective neurological indication of intractable spasticity * Lewy body disease * Lupus * Medical conditions of the same kind or class, or comparable to, enumerated conditions under state law * Migraine * Mitochondrial disease * Multiple sclerosis (MS) or persistent muscle spasms, including spasms associated with MS * Muscular dystrophy * MALS Syndrome * Myasthenia gravis * Myoclonus * Nail–patella syndrome (NPS) * Neurofibromatosis * Neuro-Bechet's autoimmune disease * Neuropathies * Obstructive sleep apnea * One or more injuries that significantly interferes with daily activities as documented by the patient's provider * Opioid use disorder * Osteoarthritis * Osteogenesis * imperfecta * Conditions as determined in writing by a qualifying patient's physician * Pain: chronic and severe pain * Pain: chronic neuropathic pain associated with degenerative spinal disorders * Polycystic kidney disease (PKD) * Pain: chronic pain * Pain: chronic pain related to musculoskeletal disorders * Pain: intractable pain * Pain: neuropathic pain * Pain: severe pain * Pain: severe and intractable pain * Parkinson's disease * Pediatric Sensory Processing Disorder * Peripheral neuropathy * Polyneuropathy * Postherpetic neuralgia * Post-laminectomy syndrome with chronic radiculopathy * Post-traumatic stress disorder (PTSD) * Residual limb pain (RLP) * Seizure disorders/epilepsy * Severe and Persistent Muscle Spasms * Severe nausea * Superior canal dehiscence syndrome * Severe psoriasis and psoriatic arthritis * Severe muscle spasticity * Sickle cell disease * Sjogren's syndrome * Spasmodic torticollis (cervical dystonia) * Spastic quadriplegia * Spasticity disorders * Spinal cord injury (SCI) or spinal cord disease, including Arachnoiditis * Spinal muscular atrophy * Spinal cord disease or severe injury * Spinal stenosis * Spinocerebellar ataxia (SCA) * Stroke * Syringomyelia * Tarlov cysts/perineural cysts * Terminal cancer * Terminal illness * Terminal illness Requiring End-of-Life Care * Terminal illness with less than 12 months of life * Terminal illness with less than 6 months of life * Tourette syndrome (TS) * Traumatic brain injury (TBI) or post-concussion syndrome * Ulcerative colitis * Vulvodynia and Vulvar Burning * Wilson's disease

Due to the fact that patients rely on specific cannabinoid profiles and potency levels to achieve the desired therapeutic effects, it is imperative that labels are accurate and consistent between states, and include all the information that a patient may need to choose the formulation that is right for them. Inaccurate labeling of cannabis products can lead to several negative health impacts. If the labeled information is inaccurate, patients may not experience the intended relief, causing frustration, diminished quality of life, and potentially even backslide in the success of their treatment. Patients may experience a worsening of their symptoms or a loss of the progress they have made in managing their condition. This can be both physically and emotionally challenging for patients who rely on cannabis as their primary or adjunct treatment option.

Incorrect labeling can also lead to interruptions in work or school attendance. Patients may experience discomfort or debilitating symptoms if they inadvertently consume a product with a different potency or formulation than what they are accustomed to using. This can have a direct impact on their productivity, performance, and overall engagement in daily activities.

Additionally, the financial aspect cannot be overlooked. Medical cannabis patients typically bear 100% out-of-pocket costs for their medication, making it crucial for them to make informed purchasing decisions. Accurate labeling allows patients to choose products that align with their specific needs and preferences, ensuring they are investing their resources wisely in the most suitable medicine for their condition.

CONTAMINANTS & HEALTH OUTCOMES

Like all other plant and agricultural commodities, cannabis is susceptible to contamination from the environment as well as from humans through processing and handling. The plant grows best in warm, humid conditions, which are the same conditions that many microbiological species thrive in. These conditions are also ideal for pests, including spider mites, aphids, and thrips. In addition, plants that are cultivated outdoors are susceptible to additional pests such as insects, rodents, and birds. The plant is also a bioaccumulator in that it can absorb chemicals, including heavy metals, from the soil and accumulate them in its stems, stalks, and leaves, which become even more concentrated during the extraction process.

Attempting to treat pests may introduce another problem for consumers if farmers attempting to prevent degradation of a highly valuable crop improperly use pesticides. Pesticide application is regulated by the Environmental Protection Agency (EPA) and typically enforced by local Departments of Agriculture. Pesticide manufacturers must specify what crops their product is intended for use on or apply for a generalized label that is broad enough to include cannabis.

At this time no pesticides have been approved for use on cannabis for human consumption at the federal level. However, 57 pesticides have been approved for use on hemp, 56 of which are biopesticides and one of which is a conventional pesticide. [1] This is because hemp is now controlled by the United States Department of Agriculture (USDA), permitting pesticide manufacturers to specify hemp as a crop for intended use on their labels. Additionally, most of the approved pesticides have labels broad enough to include hemp. However, many states, including Washington and Oregon, have approved a number of the biopesticides listed by the EPA for use on cannabis, and rather than require laboratories to test for these approved pesticides, they are required to test for pesticides that have historically been used on cannabis or other crops but are part of a banned list of substances due to their often-toxic nature.

PESTICIDES

Pesticides are a broad class of chemicals that includes herbicides, fungicides, insecticides, and rodenticides. They are crop-control agents used by cultivation operators to prevent infestation by pests and are generally highly regulated. Pesticides are designed to withstand the environment and, as such, can become pervasive. For example, while the toxic pesticide DDT was banned in the US by the Environmental Protection Agency in 1972, it has a 76-year half-life and continues to be detected in adults and children in the US.[19] A remnant of DDT, called DDE, was recently identified in cannabis in Washington State causing regulators to put a hold on productions from licensees in a region where DDT had been commonly used.[20]

Medical cannabis patients — especially younger or older people and immunocompromised individuals — may be particularly vulnerable to the negative effects associated with contaminant exposure.

Many pesticides have cumulative health effects meaning the more a person is exposed, the greater the potential health risk is. Pesticide exposure may be either acute or chronic and can result in varying degrees of toxicity. Acute toxicity is when a single dose causes an adverse health event, while chronic toxicity is a result of long-term exposure to a chemical. Pesticides may cause endocrine disruption, neurological disturbances, and reproductive and developmental harm. Some pesticides may also be carcinogenic.[21]

RESIDUAL SOLVENTS

There are numerous ways to extract the cannabinoids and terpenes from the flowers of the cannabis plant. This generally involves the use of either a solvent-based or solventless process. Solventless processes include grinding or sifting the flowers to remove the trichomes and generating various types of hash. Solvent extractions involve the use of a solvent such as ethanol, carbon dioxide (CO2), or various hydrocarbons like butane and propane to remove the cannabinoids and terpenes from the flowers and into the solvent.

After the extraction is completed, depending on the solvent there are various downstream processing steps that must occur to remove any plant material or other matter that was co-extracted, along with any remaining residual solvents.

CARBON DIOXIDE AND ETHANOL

When extractions are done using CO2 and ethanol, the result is oftentimes a waxy substance that must then go through a process called winterization to remove the waxes and other byproducts that were co-extracted. Higher-tech processes involving specialized equipment for CO2 extraction are now able to reduce the need for further downstream processing, though this process is still necessary for ethanol extracts. The FDA limits the amount of ethanol that may be present in over the counter (OTC) drug products; however, this limit is not applied to state-produced cannabis products and is not defined for hemp products. Instead, states have been left to identify the amount of ethanol remaining in the product that may lead to adverse health events and set reasonable limits accordingly.

Ethanol should not be used for products intended for inhalation as there is little research on the health effects of inhaled alcohol. Caution should be taken when using ethanol for products intended for oral consumption, particularly products intended for children or that children may use. Consumption of pure ethanol can lead to coma and death,[26] a risk that is exacerbated in children as they can only tolerate small amounts. The FDA limits the amount of ethanol in OTC drug products intended for children 6 years and under at 0.5%, and 5% for children 6 to 12 years of age.[27] Tinctures intended to be consumed orally should be tested to limit the amount of ethanol that is present in the finished product.

For CO2-extracted products, the winterization process evaporates the CO2, so it is no longer present in the concentrate and does not pose a hazard. The process often involves using ethanol as a solvent to absorb the waxes, and the cannabinoid-containing portion of the extract is then heated to remove the excess ethanol and separate it from the waxy layer. This finished product is then tested for ethanol concentration to avoid amounts that could be toxic, as concentrates are typically consumed via inhalation.

HYDROCARBONS

Many states regulate whether or not hydrocarbons may be used for cannabis extractions. Oftentimes, these regulations stipulate which are approved for use and which are not, along with determining which need to be tested for. Because hydrocarbons are not typically used in pharmaceutical extractions, the cannabis industry is left to determine how to regulate them and what levels constitute a risk.

Butane is one of the most commonly-used hydrocarbons for cannabinoid extraction. While butane has a low toxicity, in high acute doses it can affect the central nervous system (CNS) and cardiac system and can lead to severe brain damage and fetal abnormalities. The process of manufacturing butane hash oil (BHO) can be dangerous if not performed using proper equipment and safety precautions, and the extract may contain potentially hazardous amounts of residual butane.

RESIDUAL SOLVENTS

Propane is another hydrocarbon used in cannabinoid extractions. The gas is not toxic at low levels; however, it can displace oxygen in the lungs, causing breathing issues, rapid heartbeat, dizziness, and headache.[29] Similar to butane, the extraction process can be dangerous if not performed by qualified, trained personnel using specialized equipment, such as a closed-loop extraction system.

Once the oil is extracted, technicians must use a vacuum oven or similar apparatus to purge the remaining solvents out of the concentrate. These types of extracts are typically inhaled using a traditional smoking apparatus such as a pipe or bowl or using a dab-rig, which involves heating a small amount of oil on a metal surface to ignite the dab and vaporize it so that it can be inhaled.

There are over 14,000 videos that appear when searching "exploding butane cannabis concentrate," some of which are videos of consumers igniting a concentrate that was not purged properly of remaining solvent.[30]

HEAVY METALS

Heavy metals such as lead (Pb), cadmium (Cd), arsenic (As), mercury (Hg), chromium (Cr), copper (Cu), nickel (Ni), iron (Fe), manganese (Mn), cobalt (Co), tin (Sn) and zinc (Zn), are naturally occurring throughout the Earth's crust. They are typically found in the low parts per million (ppm) range, but in contaminated soil can be as high as ten thousand (10,000) ppm. Most human exposure over the past few decades has been the result of natural and anthropogenic activities including:[22]

SOURCES OF METALS

- Mining
- Refining and smelting
- Metal corrosion
- Cement manufacturing
- Petrochemical production
- Fossil fuel combustion
- Power plant emissions
- Leaded paint
- Leaded gasoline
- Soil erosion
- Volcanic eruptions

Studies have reported that some of these metals, including cobalt, iron, chromium, and manganese,[23] are needed for physiological functions such as hemoglobin formation, cross-linking of collagen and keratin, and oxidative stress-related enzymes.[24]

However, exposure to toxic metals such as lead (Pb), cadmium (Cd), arsenic (As), and mercury (Hg) can have serious adverse effects, even in small amounts. They can interact with DNA and nuclear proteins, resulting in damage and conformational changes that can interrupt regular cellular functions and cause cell cycle modulation, carcinogenesis, and apoptosis (cell death). Lead and mercury in particular are known as neurotoxins, which means they readily cross over the blood-brain barrier and affect the development and growth of brain neurons. Even at low levels, they are associated with reduced brain development, lower intelligence, and learning disabilities.

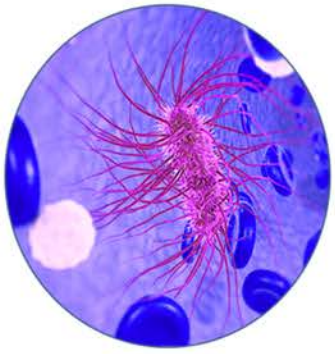
HEAVY METALS

Cannabis and hemp are known as hyper-accumulators or phyto-remediators because of their ability to absorb heavy metals from the soil and accumulate them in the flowers, stems and leaves of the plant. This can be useful when trying to remediate contaminated soil¬ — most notably, hemp was used at the site of the Chernobyl nuclear disaster to clean up radionuclide and metal contaminants.[25] However, for cannabis and hemp products that are intended for human use, such as cannabinoid and terpene consumer products, this can cause major problems because of the high toxicity of heavy metals. This is of particular concern during the cultivation process because many of the phosphate-based fertilizers and nutrients used are contaminated with heavy metals. Moreover, the pressure and temperatures used in the extraction process impact the levels of heavy metals extracted from the flower into the final product. These heavy metals could then be concentrated further as the extract goes through later stages of purification, concentration and filtration, potentially picking up additional elements from the grinding, processing, and manufacturing equipment.

It should be emphasized that consumers who choose to use electronic cannabis vaping systems (ECVS) must be aware of the potential for these devices to leach toxic heavy metals from the metal components into the concentrated cannabinoid oils and extracts. The longer a concentrated product is in a vape pen, the higher the risk of metals leaching into it. As such, adequate shelf-life studies should be conducted, and consumers should be made aware of manufacturing production dates so they may factor this information into their decision-making when selecting products. In fact, many states — including Colorado, Ohio, California, Florida and Michigan — have had to recall cannabis products due to the presence of heavy metal levels above the maximum regulated limits for their respective states.

Microbiological contaminants include bacteria, fungi, yeasts, molds, and viruses. These species are ubiquitous in the environment; however, exposure to certain species has been shown to present severe health risks in specific situations. As the growing environment for cannabis evolves and changes, the types of contaminant species identified have changed, though some remain the same. This section will highlight some of the more commonly identified microbiological contaminants that present potentially more significant health outcomes. However, this list is not representative of every species of bacteria, virus, fungi, or pest that could contaminate cannabis.

ESCHERICHIA COLI (E. COLI)



Escherichia coli (E. Coli) is a bile-tolerant, gram-negative bacteria that is commonly found in the intestines of humans and other warm-blooded animals and the environment. E. Coli contamination is most often linked to animal manure, which is commonly used in cultivation practices as a soil amendment to provide additional nutrients. E. Coli can also be found in water.

When exposed to E. Coli, a person may experience mild symptoms including abdominal cramping, diarrhea, fever, or vomiting, which can lead to more serious issues including bloody diarrhea and a potentially life-threatening disease called haemolytic uraemic syndrome (HUS).[2] While most people will recover, children, the elderly, and immunocompromised individuals face an increased risk of more serious consequences including seizure, coma, and stroke.

SALMONELLA SPECIES (SALMONELLA SPP.)

Salmonella infections, also called salmonellosis, is an infection of the gastrointestinal tract that is commonly known as food poisoning. Symptoms include abdominal cramps, diarrhea, and fever. In more severe cases, salmonellosis can cause enteric fever (typhoid fever), which must be treated quickly by doctors.[3] There are over 1,800 different Salmonella species, which are gram-negative bacteria. Many people associate Salmonella with eggs and poultry; however, recalls have occurred with onions, ground beef, pork, turkey, corn, and other vegetables.[4] No federally listed recalls have been attributed to cannabis, though both Oklahoma[5] and Michigan[6] have had to recall cannabis products due to products testing positive for Salmonella.

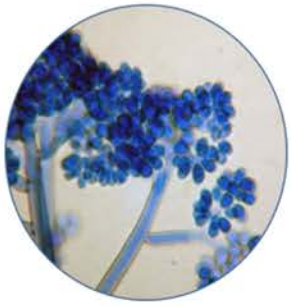
Most people will generally experience gastrointestinal discomfort, including cramps and diarrhea, and will recover without the need to visit a hospital or their doctor. However, children, the elderly, and those with compromised immune systems such as those living with cancer or HIV/AIDS may be more susceptible to complications from salmonellosis. Use of antacids, recent use of antibiotics, or having irritable bowel syndrome (IBS) may increase a person's susceptibility to salmonellosis. In severe cases, Salmonella may spread beyond the intestinal tract into the bloodstream,[7] bone marrow,[8] heart, brain,[9] and spinal cord.[10]

ASPERGILLUS SPECIES (ASPERGILLUS SPP.)

Aspergillus is a fungus (mold) with approximately 180 species. It can be found both indoors and outdoors, on surfaces and in the air, and can lead to issues such as sinus or lung infections in people who are immunocompromised.[11] In addition to sinus and lung infections, people who have weakened immune systems, including those who have recently undergone surgery, may also be susceptible to chronic pulmonary aspergillosis (CPA),[12] which is a progressive and debilitating disease.

The species that most commonly lead to issues in humans are A. fumigatus, A. niger, A. terreus, and A. flavus. Cannabis is most often consumed via inhalation and, as such, contaminated products may result in the direct administration of Aspergillus spores into the lungs.

BOTRYTIS CINEREA (GRAY MOLD)



Botrytis cinerea is an airborne necrotrophic fungus with 22 different species. Also known as gray mold, Botrytis affects many plants, not just cannabis. Gray mold can infect plants at any stage of growth. In addition, it has become resistant to many types of pesticides due to their overuse.

Botrytis can be found in greenhouse, nursery, indoor, and outdoor growing environments and can result in occupational exposure, leading to what is commonly referred to as “wine grower's lung.”[13] It may also be a source of allergies (including seasonal allergies), a trigger of asthma, [14] and a cause of lung inflammation. In addition to the health effects of Botrytis, there may be secondary issues if toxic pesticides are used to attempt to prevent or treat contaminated plants.

OTHER YEASTS AND MOLDS

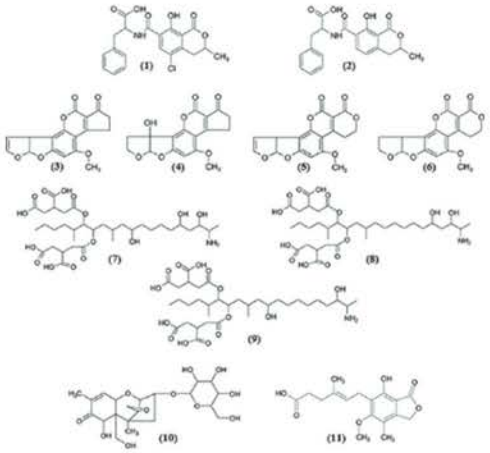
In addition to the individual species listed, cannabis is susceptible to a number of other yeasts, molds, and fungi including Trichothecium roseum (white mildew or pink rot) and Alternaria alternata (brown blight). Because there are so many different types of yeasts, molds, and fungi in the environment, it is generally not feasible to individually test for each. As such, some states have instituted testing for Total Yeasts and Molds, often abbreviated as TYM or TYMC (Total Yeast and Mold Count). This testing is also a requirement for many dietary supplements and pharmaceutical drugs, particularly those that are inhaled. Like Botrytis, these contaminants may cause issues for both workers who have been overexposed and to consumers with low-functioning immune systems.

AFLATOXINS AND OCHRATOXIN A

Aflatoxins and Ochratoxin A are mycotoxins produced by fungi found all over the world. According to the World Health Organization, over 25% of the world's food crops must be destroyed annually due to aflatoxins.[15] Aspergillus flavus and A. parasiticus are the two molds most commonly responsible for aflatoxin production. These strains are often found in humid, overly wet conditions and can also result from improper storage occurring post-harvest. Ochratoxin A is produced by numerous different fungal species including Aspergillus niger, A. ochraceus, A. carbonarius, and Penicillium verrucosum.[16]

There are at least 14 different types of aflatoxins; however, aflatoxins B1, B2, G1, and G2 are most dangerous to humans. These aflatoxins have been found in numerous food crops including corn, often used as animal feed, leading to contaminated meat and animal products as well as potentially contaminated manure. In locations where lower-quality grain products are fed to livestock, the issue is perpetuated more often. Like aflatoxin, Ochratoxin A is found in food crops intended for both human and animal consumption.

Aflatoxins are carcinogenic and can affect every system in the body. They are mutagenic and genotoxic, meaning they may cause birth defects, and also act as an immunosuppressant. They may stunt children's growth and can have deleterious effects on the liver.[17] Ochratoxin A may cause kidney damage, and the International Agency for Research on Cancer has stated that it is a possible Group 2B carcinogen based on animal studies.[18]



MOISTURE CONTENT AND WATER ACTIVITY

The amount of water present, also known as the moisture content of a product, can indicate its ability to support the growth of microorganisms of public health concern. High moisture content is capable of supporting rapid growth; however, if the content is too low, the flowers lose their appeal as they become dry and brittle. Additionally, when overdried, many of the terpenes are evaporated out and the product loses its smell and taste, along with any medicinal benefits the terpenes may have imparted. In cannabis flowers, the moisture content should be below 15%, with some suggesting that 10-12% is the ideal range.[33]

The moisture content of food and topical products is its water activity (aw) and is a measurement of the amount of unbound water molecules. Unbound water molecules can support the growth of microorganisms and is regulated by the FDA for food products. Foods that are greater than 0.95 aw must adhere to the Code of Federal Regulations, Chapter 21 parts 108, 113, and 114. Foods that are less than 0.85 aw are not subject to these requirements.[34]

States including California, Oregon, Nevada, and Washington have implemented water activity requirements for cannabis flowers and cannabis-derived products. Typically, these limits are lower than the FDA limits and generally require an aw of 0.55-0.65.

FOREIGN MATTER

Foreign matter is anything that is not cannabis present in the finished product. This can include things such as netting or trellis that was not completely removed during harvest, remnants of bugs or insects or their droppings, hair, skin cells, or metal shavings. These adulterants can be toxic to some immunocompromised individuals and also pose a hazard if things like metal shavings from automatic trimming machines make their way into flowers or downstream products. Most states require that flowers and products be examined for any foreign matter that may be present and limit the amount present based on the weight of the product.

ADDITIVES AND ADULTERANTS

Because of the high value of cannabis, some unscrupulous operators may look to use additives or adulterants to add weight to or dilute their product. The vaping crisis that emerged in 2019 and 2020 highlighted a major gap in cannabis testing — the presence of additives in cannabis concentrates, which are used to dilute their potency for use in vape cartridges. These additives included vitamin E acetate, squalene, and food flavorings that are approved for other consumer commodities but not for inhalation.[31] The Centers for Disease Control (CDC) determined that the outbreak was most likely linked to vape cartridges purchased from the illicit market. These cartridges were found to contain adulterants such as vitamin E acetate, coconut oil, and limonene.[32]

Vitamin E acetate is found in many foods and cosmetic products and does not generally cause harm when applied topically or consumed orally as a dietary supplement. When inhaled, however, Vitamin E acetate can cause damage to lung function. Like vitamin E acetate, while coconut oil does not generally cause harm when ingested or applied topically, there are no studies that have examined its toxicity when inhaled. Limonene is a naturally occurring terpene in cannabis that is sometimes removed or evaporated off during the extraction process and, in order to make concentrates have the characteristic Cannabis smell, is added back in before sale. Unfortunately, most of the terpene products that are added back into the product are food grade and their safety has not been evaluated for toxicity when consumed via inhalation. As a result, they are suspected as a cause of some of the vaping lung injury cases.

TESTING REQUIREMENTS SUMMARY

Despite 42 states and territories having some form of medical or adult-use cannabis regulations, not every state requires testing. This poses important health equity concerns, as medical cannabis patients and consumers in some states may be exposed to higher levels of contaminants than patients and consumers in other states. For this analysis, only medical and adult-use cannabis programs were evaluated. States and territories that permit only CBD products or low-THC products were not included. This is because, out of all the states that permit CBD/low-THC products, Iowa, Louisiana, and Virginia are the only ones that require testing. Additionally, hemp-based CBD products do not typically fall under the purview of state cannabis regulations but rather federal regulations, which have not been developed at this time outside of limitations on THC content for hemp flowers and derived products. The only location that does not require potency testing is Puerto Rico, although they are still in the process of developing rules for the implementation of their medical cannabis program and may require testing in the future.

Required Testing (42 States / Territories)	Number of States Requiring Testing	Percent of States Requiring Testing
Cannabinoids	41	97.60%
Microbials	38	90.50%
Residual Solvents	35	83.30%
Pesticides	34	81.00%
Heavy Metals	30	71.40%
Aflatoxins	28	68.30%
Moisture Content/Water Activity	25	59.50%
Foreign Matter	16	38.10%
Homogeneity	12	28.60%
Terpenes	9	21.40%

TABLE 1: SUMMARY OF REQUIRED TESTING

As these charts and graphs indicate, outside of potency testing, many states fall short when it comes to evaluating the identity, strength, and purity of the products they permit for sale. Microbiological and residual solvent testing are the most frequently required contaminant tests at 90.5% (38 states) and 83.3% (35 states), respectively. Pesticides are required to be tested for in 34 out of 42 (81%) different jurisdictions, followed by heavy metals testing in 30 (71.4%). Aflatoxin testing is required by 68.3% of locations (28 states) and moisture content/water activity is mandated by 59.5% (25 states). Least frequently, testing for foreign matter, homogeneity, and terpenes is also required in 38.1% (16), 28.6% (12), and 21.4% (9) of states.

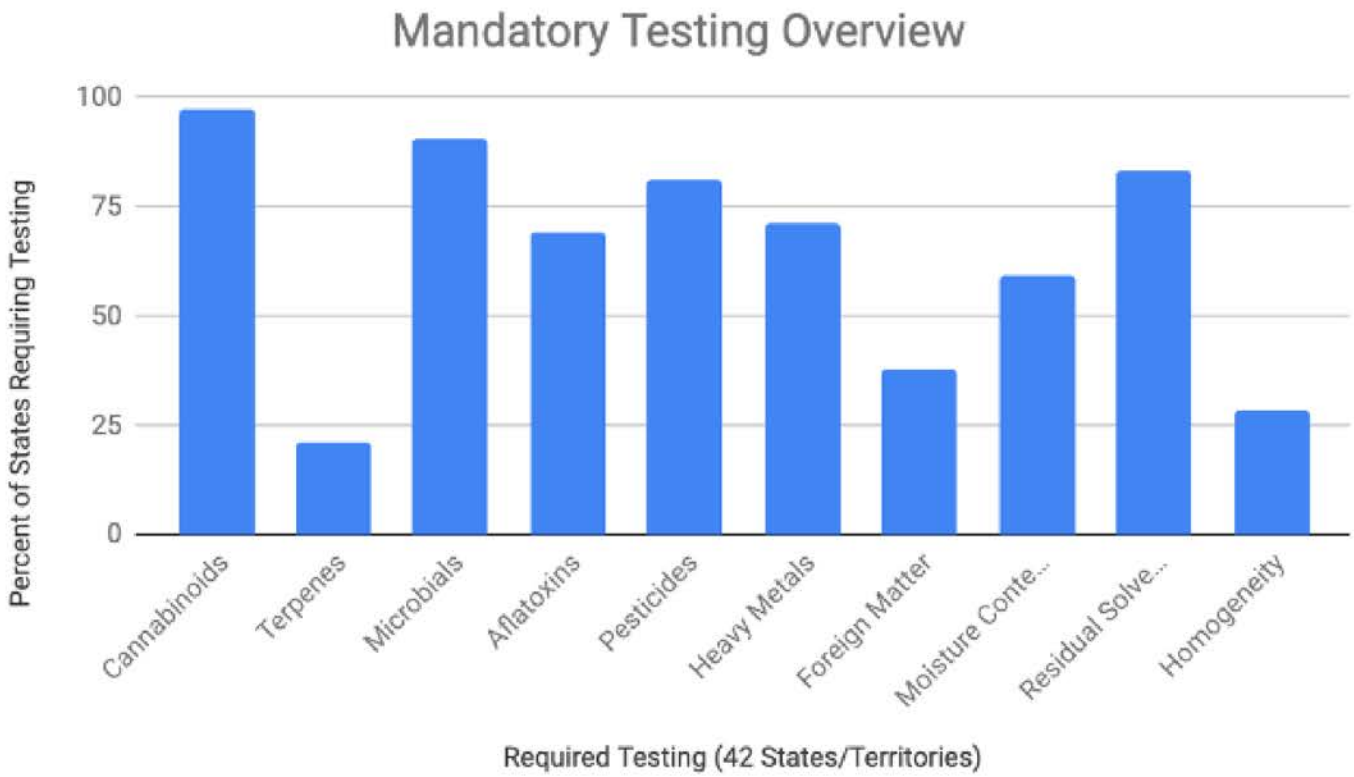


FIGURE 3: SUMMARY OF REQUIRED TESTING

Each of these different tests are required across multiple other industries, such as the food production, dietary supplement, and pharmaceutical industries. Most jurisdictions seem to be in agreement with a minimal amount of testing; however, the limits and specifics of the test types, such as the specific types of microbiological contaminants or pesticides to be tested for, can vary drastically. So, while a state may have a specific test requirement, it may still fall short of what is needed to keep patients and consumers safe.

TESTING LAB REQUIREMENTS

There are numerous standards to which laboratories may need to comply with. The most common is the ISO/IEC 17025 standard, an international standard for laboratories that outlines quality management systems that must be in place along with documentation and recordkeeping requirements. However, there are additional standards, including the Good Laboratory Practices (GLP) standards outlined in the Code of Federal Regulations and required by Washington and the Patient Focused Certification (PFC) as required by Guam. Colorado does not explicitly require ISO 17025 accreditation; however, it is an option, and many labs will obtain this accreditation as a means of demonstrating compliance. Arkansas requires either ISO 17025, or a certification from either the National Institute of Drug Abuse (NIDA) or National Environmental Laboratory Accreditation Program (NELAC) and Oregon requires laboratories to carry certification based on The NELAC Institute (TNI) standards.

States Requiring ISO 17025 or Other Laboratory Certifications	**AL, AR, AZ, CA, CO, DC, DE, FL, GU, LA, MD, ME, MI, MN, MO, MT, NJ, NV, OH, OK, OR, PA, SD, UT, VA, VT, WA, WV**

TABLE 2: LABORATORY REQUIREMENTS

Each of these laboratory standards requires labs to demonstrate the test method's suitability for purpose including validating each method and establishing its accuracy, precision, and robustness. Method validation is a critical component involved in ensuring that components are analyzed, and results are reproducible and reported correctly. They also require laboratories to obtain standards from ISO 17034 accredited suppliers. This production standard ensures that the standards used in laboratory analyses are made and certified to be accurate and precise, allowing for results to be reliably calculated.

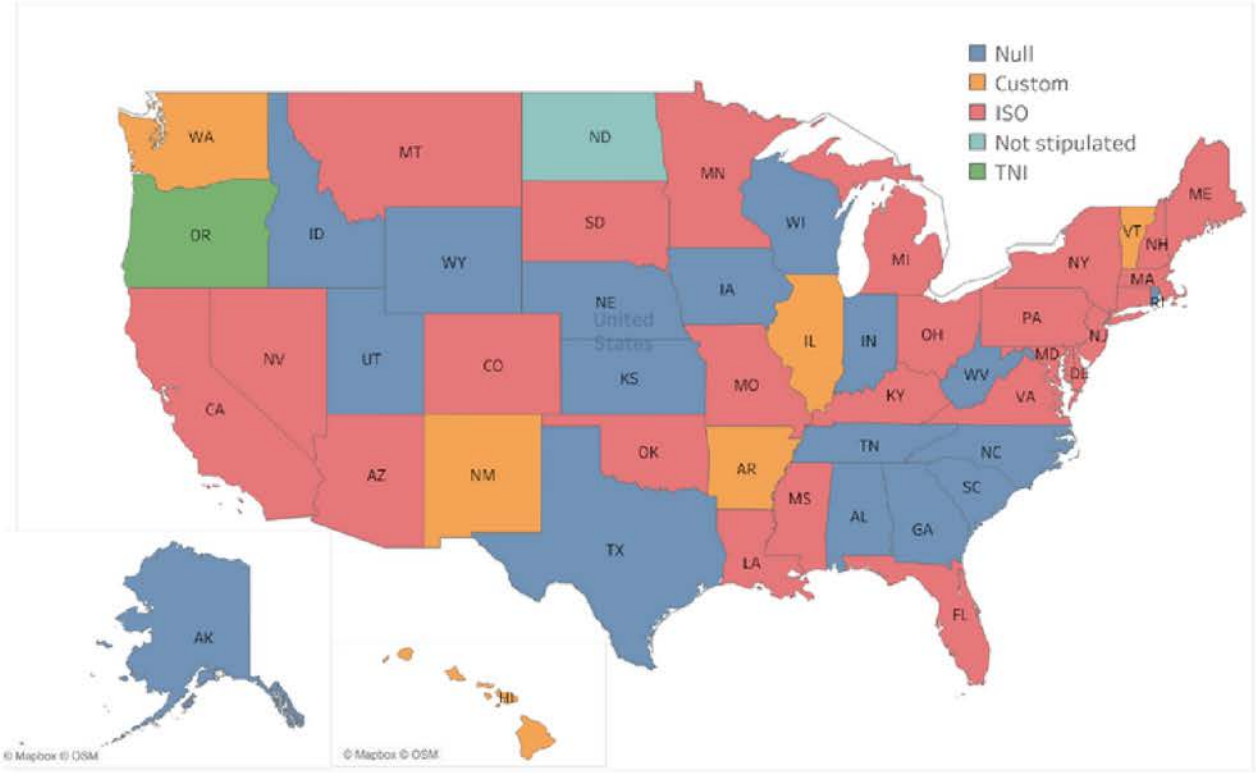


FIGURE 4: ACCREDITATION REQUIREMENTS

An additional requirement of these standards, and one that is often written into cannabis regulations — particularly those states and territories that do require ISO 17025 — is the requirement to enroll in a proficiency testing (PT) program. Proficiency testing programs are independent of the labs themselves and are tasked with sending samples to laboratories to evaluate their test methods and ensure results meet conformance specifications.

One of the major challenges with PT programs is the limitations that the Drug Enforcement Agency (DEA) places on products shipped throughout the US. At this time, cannabinoid standards may have a maximum concentration of 1mg/mL in liquid solution in order to be shipped across state lines. This means that cannabinoid PT samples may not exceed 1mg, though many states place limits of 10mg THC per serving with a general limit of 100mg THC per package (10x10mg servings per container). PT samples are also generally in solution and can be injected directly onto the instrument, which verifies that the instrument is calibrated properly but does not verify that the extraction procedures used by the lab are suitable for analysis. It also means that the matrix that the PT sample is in is not representative of the various types of products on the market and as such, a laboratory could be using an inefficient sample extraction method to test for cannabinoid content. Different PT samples used in calibration can impact the efficacy of all of the tests run on that equipment, and inappropriately prepared PT samples could introduce large amounts of variance in the test results.

This type of limitation means that PT programs may not be able to identify laboratories that are underperforming or extraction methods that may not be suitable for other matrices. Until the DEA eases its restrictions on the cannabinoid content that may be present in samples shipped throughout the US, states will need to implement their own PT programs and institute random testing programs for products that are currently on the market. Given that there is currently much controversy surrounding which test methods are acceptable, part of this program will be to develop and validate test methods at a state or approved university laboratory. Another part of this program will be to develop and distribute round robin samples that are representative of products in the regulated marketplace.

Most testing labs utilize high-pressure liquid chromatography (HPLC) methods over gas chromatography (GC) methods and many instrument manufacturers have developed test methods that come as part of a package when a new instrument is purchased. There are also published test methods that are fit-for-purpose and may be utilized by state and university laboratories as well. A lab's potency testing method tends to be considered proprietary, and there is no reason they should be able to continue using these proprietary methods when there are other means of evaluating test method performance.

Another aspect of a robust PT program is to develop PT samples that span many of the different matrices common to cannabis products and to identify additional test types that are needed. Cannabinoid-based products are available in numerous different types of matrices including flower, concentrates such as wax, shatter, live resin, and hash, edible products such as cookies, gummy candies, beverages, and hard candies, topical products including lip balms and lotions, and a myriad of other product types. While it would be challenging to develop PT samples of each matrix type, the most common ones should be evaluated, particularly the edible products as these tend to present more complex matrices and have the most stringent packaging and labeling requirements.

Another way for states to evaluate laboratory test method performance is to require more than just potency PT samples. In states that require contaminant testing, including testing for microbiological contaminants, pesticides, residual solvents, heavy metals, and foreign matter, labs should be required to enroll in PT programs for each of the mandatory tests that they are conducting. These PT samples should also include various matrices that are representative of the types of products available on the market.

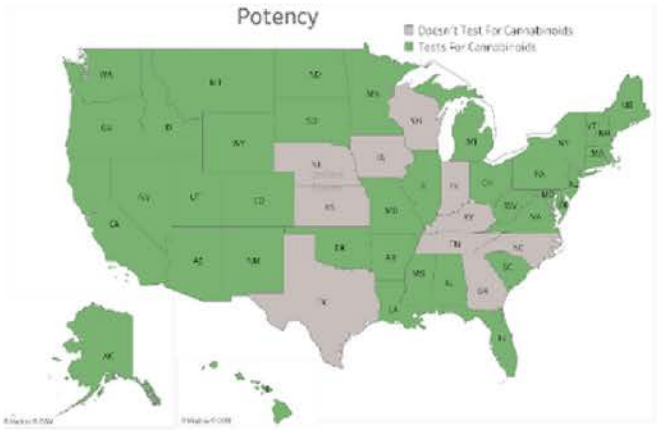


FIGURE 5: STATES THAT REQUIRE POTENCY TESTING

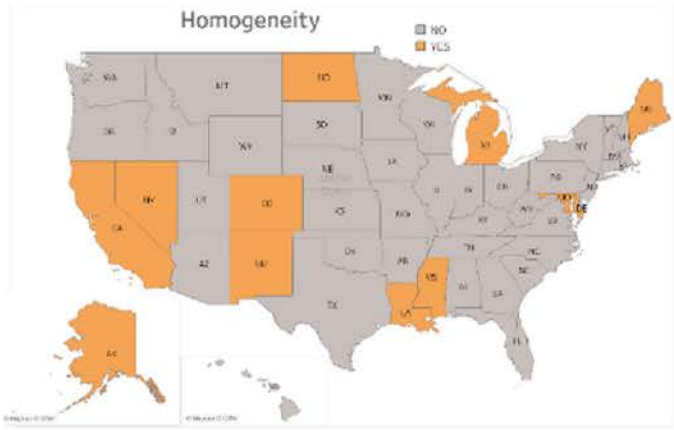


FIGURE 6: STATES THAT REQUIRE HOMOGENEITY TESTING

While most states do require some level of potency testing, particularly for the five most well-known cannabinoids — THC, THCA, CBD, CBDA, and CBN, many fail to require homogeneity testing. When testing regulations were first under development, the five primary cannabinoids were the only standards available. However, as more standards have become available, states still only require reporting of these five, while some only require reporting and labeling of THC, CBD, and CBN.

For patients and consumers, this paints an incomplete picture of the products that they are purchasing and using. Patients are encouraged to keep track of the products that they are utilizing to better identify the ones that work best for their ailments and symptoms, but how can they do this to the fullest extent without all of the information available? Currently, there are cannabinoid standards available that can detect over 10 different cannabinoids (some as many as 17), yet many states still require reporting of only five.

This is starting to be remedied by the states that are now requiring full disclosure of all testing Certificates of Analysis (Arizona, Connecticut, Guam, Illinois, Nevada, Virginia, Mississippi, and Washington), either by means of presenting a physical test report to patients and customers at the time of sale or including it on product inserts or online product listings. Although it is not required, in other locations companies are making their products' testing data available, such as in California, as many see it as a competitive edge and a good sales tactic.

One aspect of potency testing, particularly with edible cannabinoid-containing products (required by only by 11 states), is testing the homogeneity of the product. Homogeneity describes the distribution of cannabinoids in the product, particularly products that contain more than one serving such as a chocolate bar or liquid beverage. The distribution of cannabinoids should be such that each serving contains the same amount of each constituent. While this is important for THC, a potentially intoxicating cannabinoid, it is equally important for the other cannabinoids and terpenes as well.

Cannabinoid dosing is important to both patients and consumers, so it is critical that a product's potency is consistent and labeled serving sizes accurate. Some states, such as California, allow for a labeled variance of the product's potency, owing to both the flower's varied distribution of cannabinoids and laboratory instrument capabilities. California's labeled variance is +/- 20%, which means that a product that contains 10mg of THC could contain approximately 8-12mg THC. This also means that, if a product was pulled off the shelf and tested at random, that product should have a test result that falls within +/- 20% of the labeled value.

Homogeneity testing verifies this distribution by ensuring that, as required in Colorado, not more than 20% of the THC is located in a single serving. This means that, if a package contains 100mg of THC, no more than 20mg THC would be found in a single serving. For patients and consumers whose needs require accurate dosing, including those who may not be accustomed to how THC reacts in their body when ingested, it is important they get what they expect in a product. For medical professionals and researchers, it is equally important that they are able to discuss with their patients their current medicines, current dosing for both cannabinoids and terpenes, and whether the product is currently working to treat their ailment or symptoms. This will enable them to further advance cannabis research and identify products at specific cannabinoid and terpene ratios that may help other patients treat their ailments or symptoms. It will also enable clinical trials to be conducted using consistently dosed and accurately identified products.

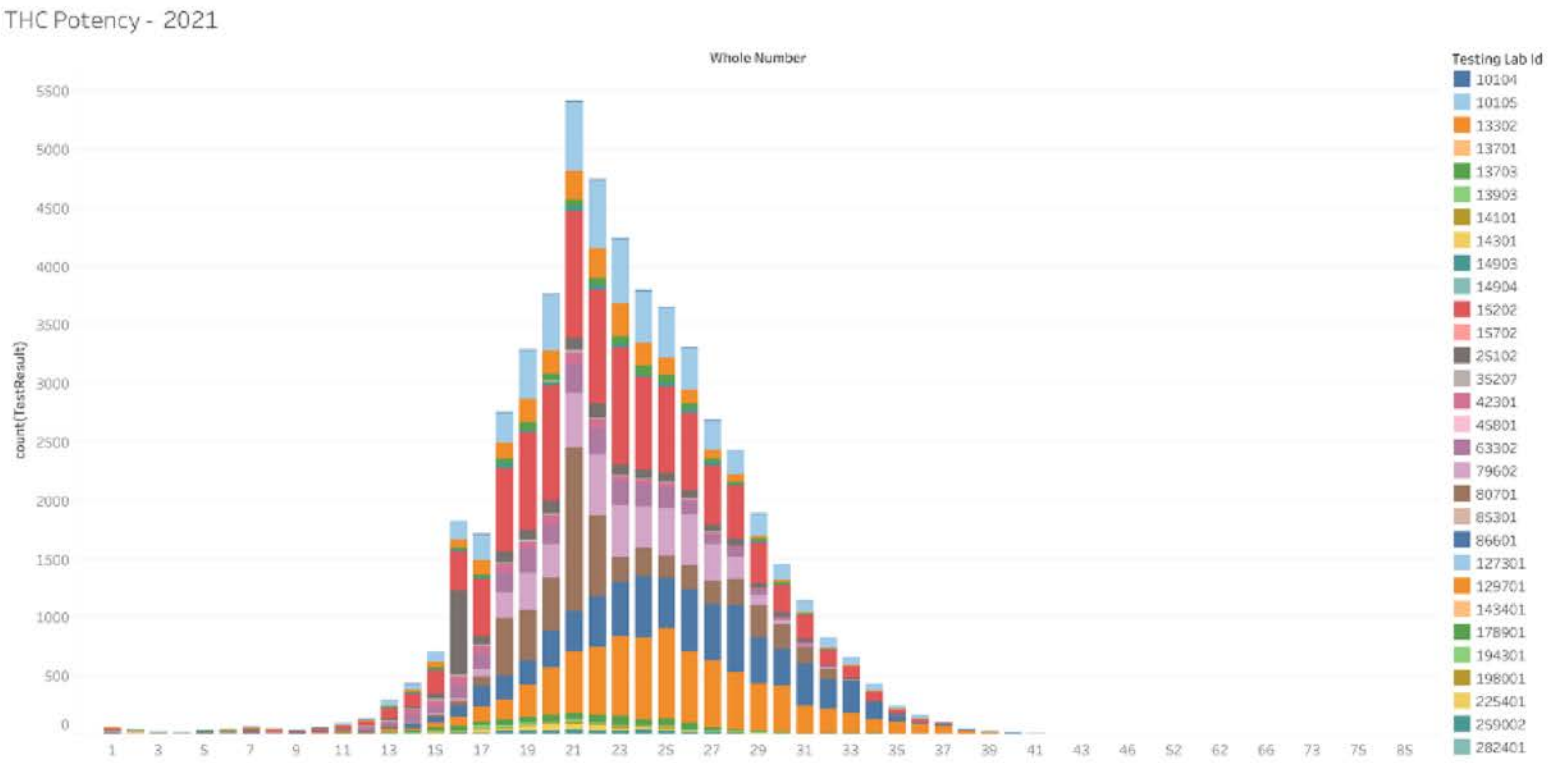


FIGURE 7: THC POTENCY INFLATION ISSUES AS SEEN ON A HISTOGRAM FROM OREGON THC RESULTS, 2021

Because many states do not require cannabis testing to be conducted using standardized methods, a growing issue is that many labs use techniques to artificially inflate the potency of products sent to them in order to increase their market value and satisfy clients. In Washington, Nevada, and Oregon, an investigative review found that the distribution of the THC content in tested products "jumps" at the 20% mark. This indicates that some unscrupulous labs are engaging in practices to produce results that increase the market value of the products delivered to them by clients and remain competitive with other labs. Some of these practices include making calculations based on moisture content or moisture loss, spiking the sample with a more potent product, using pre-prepared samples provided by their clients, swapping samples with higher-testing ones, using standards known to give higher results, intentionally miscalibrating equipment, incorrectly entering the sample weight during calculations, or even making up results entirely (a practice known as "dry labbing"). Some states, such as California, have introduced regulations that would address potency inflation by requiring the use of standardized testing methods, as described earlier. It is imperative that other states follow suit in order to provide patients and consumers with the information they need to make informed choices about the products they consume. [35]

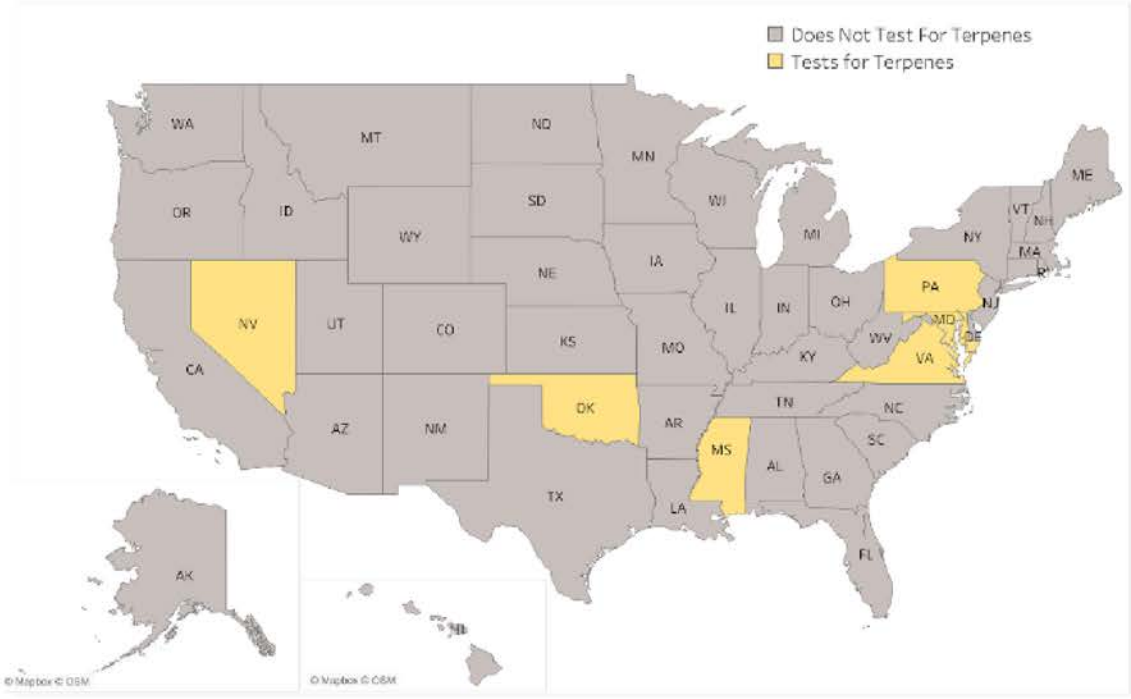


FIGURE 8: STATES THAT REQUIRE TERPENE TESTING

While potency testing is required by almost all states, only nine states mandate testing for terpenes. Potency, the measurement of a product's active ingredients, should include not only cannabinoids but also terpenes. The Entourage Effect, first identified in 1998 by Dr. Raphael Mechoulam and Dr. Shimon Ben-Shabat,[36] describes how the interaction of cannabinoids and terpenes provide more medical benefit than single-molecule compounds. Terpenes have been shown to have medicinal value and as such they should be identified and quantified in cannabis and hemp products to provide additional information for patients, consumers, researchers, and medical care providers.

With only eight states requiring disclosure of testing COAs, patients, consumers, researchers, and medical professionals do not have access to all the information needed to make informed decisions about their health. And yet, like cannabinoids, there are many terpenes as well as standards available for testing and quantifying them. States must implement testing policies that include terpene testing, product labeling, and COA disclosure in order to give patients a complete picture of their medical cannabis products.

An additional consideration around terpene testing involves labeling products that have had terpenes added back into them. Many extraction processes strip the concentrated product of naturally occurring terpenes, leading some processors to add them back into the end product. The amount of terpenes added back into the finished product should be tested for and labeled accurately so that consumers are aware of the type and quantity of terpenes in the product. Additional restrictions should also be in place to ensure that terpenes that are not suitable for inhalation, such as those derived from non-cannabis sources, are not used in the manufacture of cannabis products.

PESTICIDES TESTING

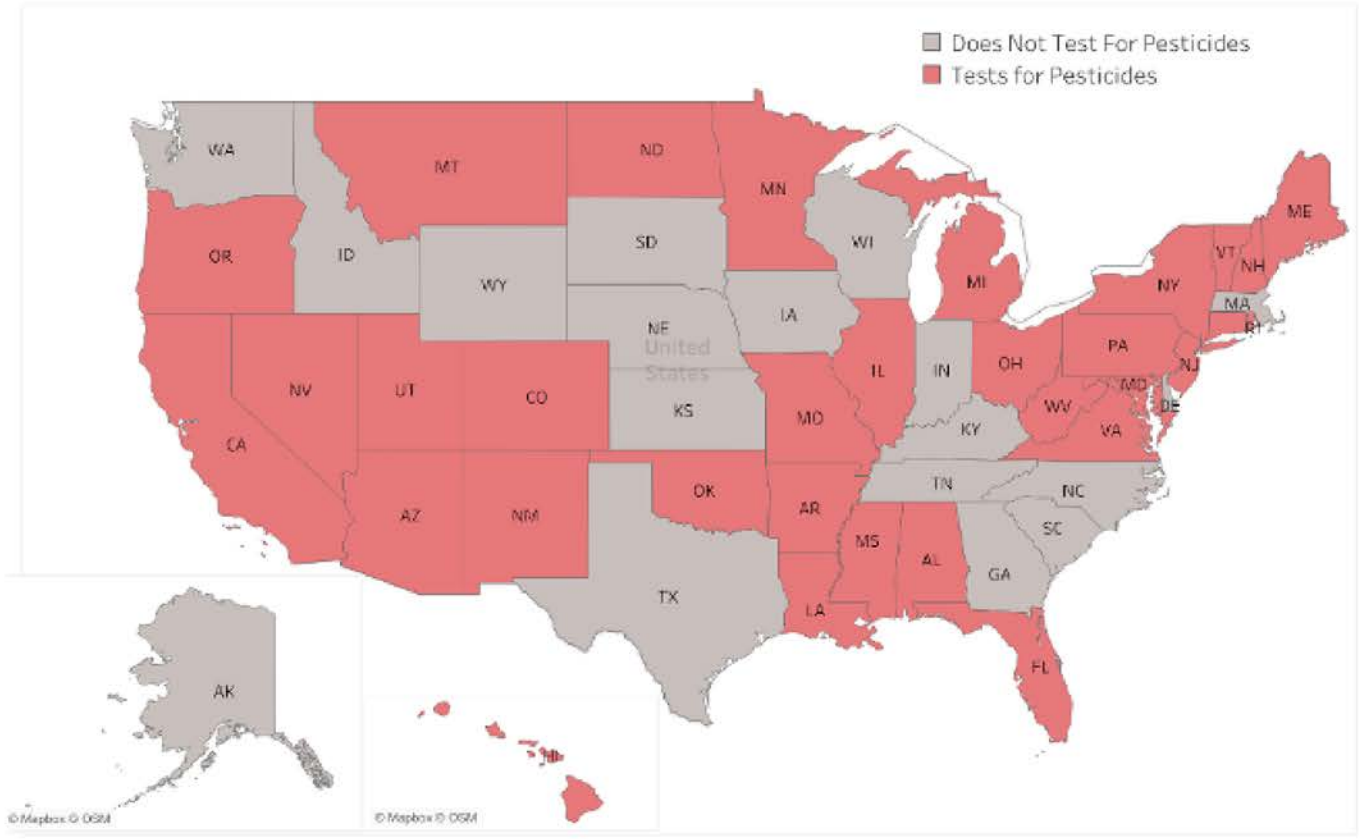


FIGURE 9: STATES THAT REQUIRE PESTICIDE TESTING

The Environmental Protection Agency (EPA) is responsible for regulating pesticides in the US, though most state Departments of Agriculture are tasked with enforcing these regulations. Pesticides are the second most required test of all the contaminant tests, with 34 states requiring some form of it. However, what that form takes can vary dramatically from state to state. At this time there are no pesticides approved for use on cannabis by the EPA, however there are 58 biopesticides and one traditional pesticide approved for use on hemp plants.[37] Biopesticides are bacteria or naturally occurring chemicals such as neem oil that may be used as a pesticide, while traditional pesticides are generally synthetically produced and not naturally derived.

There are hundreds of pesticides on the market. This can oftentimes seem like an overwhelming number, particularly for the seven states (Connecticut, Hawaii, Illinois, Louisiana, North Dakota, Ohio, and Virginia) that require testing of the entire list outlined in 40 CFR 180, which contains 396 different pesticides. These states have either developed smaller, more concise lists of pesticides that the labs must test for, although that is not the case for all of them.

Pesticide	Lower Limit (ppm)	Upper Limit (ppm)
Imidacloprid	0.02	25
Myclobutanil	0.02	240
Permethrin	0.05	50
Piperonyl Butoxide	0.1	20
Pyrethrins	0.05	3.0

TABLE 3: COMMON CANNABIS PESTICIDES WITH EPA ACTION LIMITS

One challenge in using the Code of Federal Regulations (CFR) to identify action limits for pesticides on cannabis is that the pesticides listed in 40 CFR 180 are identified for use on a specific commodity or group of commodities, though none of these commodities are intended to be inhaled. These commodities are also raw food groups (eggs, almonds, milk, hops, legumes, etc.) and most edible cannabis products are not raw food groups but rather products made from some combination of them. Because of this, there are a range of possible action limits that a state may impose. Table 3 identifies some of the more common pesticides that cannabis laboratories must test for and their range of EPA action limits.

With so many different pesticides available, and no commodity-specific action limits, it would make sense to adopt the same action limits regulating pesticides in tobacco given that it is a product that is typically inhaled. However, no state has adopted the United States Department of Agriculture's (USDA) residue limits for pesticides in tobacco (Table 4) and only two of the pesticides, chlordane and permethrin, currently appear on any state testing lists.

The USDA is also responsible for regulating the National Organic Program (required by Maine), and the Organic Materials Review Institute (OMRI) publishes a list of all pesticides approved by the USDA for use in organic cultivation. Additional states are also establishing organic cultivation guidelines or requirements; however, these do not always address the issue of testing for substances that are not permitted for use. The United States Pharmacopeia (USP) chapter 561 is required by Minnesota (Table 5), while Rhode Island mandates testing based on the American Herbal Pharmacopoeia's Cannabis Monograph (Table 6) with an action limit at a general Limit of Detection (LOD) for most analytical testing methods, oftentimes set at 0.01ppm.

Table 5: USDA's Residue Limits for Pesticides on Tobacco

Pesticide (organochlorine pesticides in bold)	Residue limit (parts per million)	Approved for nontobacco use(s)
1. Chlordane	3.0	No
2. Dibromochloropropane (DBCP)	1.0	No
3. Dicamba	5.0	Yes
4. Endrin	0.1	No
5. Ethylene dibromide (EDB)	0.1	No
6. Formothion	0.5	No
7. Hexachlorobenzene (HCB)	0.1	No
8. Methoxychlor	0.1	Yes
9. Toxaphene	0.3	No
10. 2,4-D	5.0	Yes
11. 2,4,5-T	0.1	Yes
12. Sum of aldrin and dieldrin	0.1	No
13. Sum of cypermethrin and permethrin	3.0	Yes
14. Sum of DDT, TDE, and DDE	0.4	No
15. Sum of heptachlor and heptachlor epoxide	0.1	No

Source: 7 CFR 29.427, USDA, and EPA.

TABLE 4: USDA'S RESIDUE LIMITS FOR PESTICIDES ON TOBACCO

Pesticide Testing Requirements	Minnesota (USP <561>)
Acephate	0.1ppm
Chlordane	0.05ppm
Chlorpyrifos	0.2ppm
Cyfluthrin	0.1ppm
Daminozide	1ppm
Diazinon	0.5ppm
Dimethoate	0.1ppm
Malathion	1ppm
Permethrin (cis + trans)	1ppm
Phosmet	0.05ppm
Piperonyl Butoxide	3ppm
Pyrethrins	3ppm

TABLE 5: USP <561> PESTICIDE ACTION LIMITS

In addition to Rhode Island's requirement that testing be based on the AHP Cannabis Monograph, Montana and New Mexico require testing of the same list of pesticides with different action limits and minor variations in the list. Montana and New Mexico have also chosen to separate out their pesticide residue action limits based on the product's delivery method, i.e., inhalable products (dry, processed flower) or non-inhalable products (extracts, edibles, etc.).

Pesticide Testing Requirements	AHP Monograph	Rhode Island	Montana (unprocessed, dry flower)	New Mexico (Inhalable Products)	Montana (extracts)	New Mexico (Non-Inhalable Products)
Abamectin	0.01ppm	0.01ppm	0.5ppm	0.1ppm	2.5ppm	0.15ppm
Acequinocyl	0.01ppm	0.01ppm	2ppm	2.0ppm	10ppm	2.0ppm
Bifenazate	0.01ppm	0.01ppm	0.2ppm	0.2ppm	1ppm	0.2ppm
Bifenthrin	0.01ppm	0.01ppm	0.2ppm	0.1ppm	1ppm	0.1ppm
Chlormequat chloride	0.01ppm	0.01ppm	1ppm		5ppm	
Cyfluthrin	0.01ppm	0.01ppm	1ppm		5ppm	
Daminozide	0.01ppm	0.01ppm	1ppm		5ppm	
Etoxazole	0.01ppm	0.01ppm	0.2ppm	0.1ppm	1ppm	1.0ppm
Fenoxycarb	0.01ppm	0.01ppm	0.2ppm		1ppm	
Imazalil	0.01ppm	0.01ppm	0.2ppm	0.1ppm	1ppm	0.1ppm
Imidacloprid	0.01ppm	0.01ppm	0.4ppm	0.1ppm	2ppm	3.0ppm
Myclobutanil	0.01ppm	0.01ppm	0.2ppm	0.1ppm	0.6ppm	0.4ppm
Paclobutrazol	0.01ppm	0.01ppm	0.4ppm	0.04ppm	2ppm	0.04ppm
Piperonyl Butoxide				3.0ppm		8.0ppm
Pyrethrins	0.01ppm		1ppm	0.5ppm	5ppm	1.0ppm
Spinosad	0.01ppm	0.01ppm	0.2ppm	0.1ppm	1ppm	3.0ppm
Spiromesifen	0.01ppm	0.01ppm		0.1ppm		0.2ppm
Spirotetramat	0.01ppm	0.01ppm	0.2ppm	0.1ppm	1ppm	0.2ppm
Trifloxystrobin	0.01ppm	0.01ppm	0.2ppm	0.02ppm	1ppm	0.02ppm

TABLE 6: AHP CANNABIS MONOGRAPH PESTICIDE ACTION LIMITS AND STATE COMPARISONS

Pesticide analysis in Arizona, Arkansas, Michigan, Missouri, Oregon, Utah, and Washington (See Appendix I: Additional Testing Tables) requires testing for approximately 60 different compounds, each of which has the same action limit. New Hampshire requires testing of the same list as these states; however, their action limit is 0.01ppm across all compounds. Mississippi also requires testing for 60 different pesticides with different action limits based on the agent. These action limits range from 0.1 to 2.0ppm.

California and Florida require testing of the same list of almost 70 compounds, but this testing is broken down by product delivery method (inhalation or non-inhalation). In addition, there are differences in the action limits imposed (See Appendix I: Additional Testing Tables). Washington, DC and Maryland require testing of a slightly smaller list of 48 pesticides, each of which has the same action limit, except for daminozide which has a limit of 0.1ppm in Washington, DC and 1.0ppm in Maryland.

Pesticide Testing Requirements	Colorado	Oklahoma	South Dakota
Abamectin	0.07ppm	0.5ppm	0.5ppm
Azoxystrobin	0.02ppm	0.2ppm	0.2ppm
Bifenazate	0.02ppm	0.2ppm	0.2ppm
Etoxazole	0.01ppm	0.2ppm	0.2ppm
Imazalil	0.04ppm	0.2ppm	0.2ppm
Imidacloprid	0.02ppm	0.4ppm	0.4ppm
Malathion	0.05ppm	0.2ppm	0.2ppm
Myclobutanil	0.04ppm	0.2ppm	0.2ppm
Permethrin (cis + trans)	0.04ppm	0.2ppm	0.2ppm
Spinosad	0.06ppm	0.2ppm	0.2ppm
Spiromesifen	0.03ppm	0.2ppm	0.2ppm
Spirotetramat	0.02ppm	0.2ppm	0.2ppm
Tebuconazole	0.01ppm	0.4ppm	0.4ppm

TABLE 7: STATE CANNABIS TESTING REQUIREMENTS

Beyond the states already reviewed, Table 7 identifies the pesticides and their action limits for Colorado, Oklahoma, and South Dakota. These do not follow the other states as they have a much shorter list, and Colorado has typically lower action limits than Oklahoma and South Dakota.

These tables illustrate that there is no consistency amongst more than a handful of states, and even then, there are differences. Additionally, while all of the action limits for the states have been converted to a consistent unit of measurement for this report (parts per million for pesticides), they are written into various state regulations in either parts per million or parts per billion, further adding to these inconsistencies.

There is limited research into the pesticides that are commonly used on cannabis plants and how those pesticides will affect someone that is inhaling them versus eating them versus applying them topically. Pesticides may also undergo various chemical changes when ignited. Research is needed to determine what these changes are and how they will affect the person inhaling them. While this research is being conducted, states should identify a list of commonly used pesticides and require labs to test for them. Action limits need to be set at a reasonable level that promotes consumer safety along with worker exposure safety.

For regulators, establishing these lists can be problematic, the volume of options and production costs may mean finished goods are too expensive, too few and patients and consumers could potentially be exposed to harmful pesticides, leading to potential adverse events and chronic health conditions. The list of pesticides to be tested for in states like California, Florida, Michigan, Oregon, and Maryland is extensive enough to provide a comprehensive analysis of cannabis products. Until the science around reasonable action limits can be established, states could adopt an average action limit, or utilize the EPA's upper or lower limits to start. From there, states may look to the testing labs to identify the compounds that have not been found on cannabis products and remove them from the list, thereby eventually easing the process for cannabis market producers while still protecting patient and consumer safety.

RESIDUAL SOLVENT TESTING

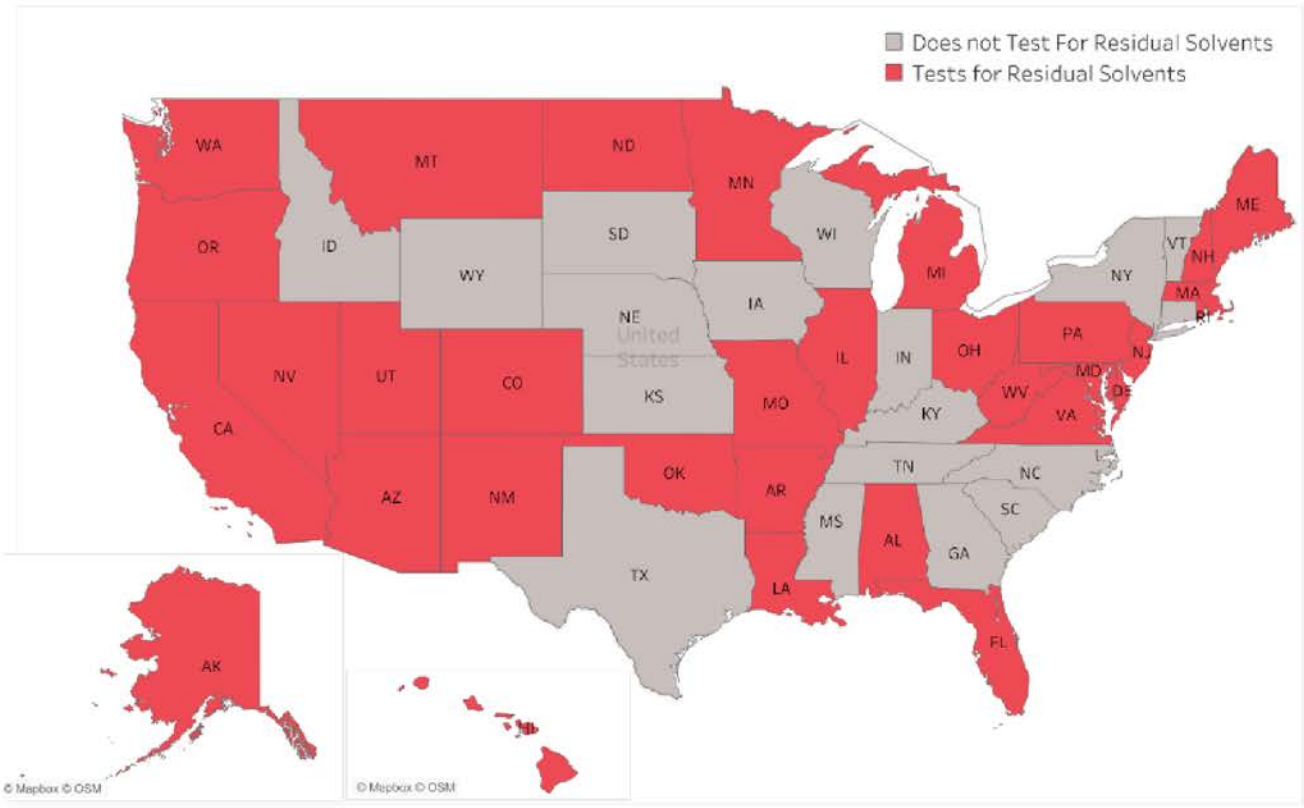


FIGURE 10: STATES THAT REQUIRE RESIDUAL SOLVENT TESTING

With 35 states requiring residual solvent testing, it is the second most required contaminant test. Like pesticide testing, there are a number of states that have elected to test for the same compounds and set the same action limits, while others have chosen a different set with different limits. Delaware, Pennsylvania, and Washington, DC require testing based on USP <467>, while Illinois and Virginia require testing based on the AHP Cannabis Monograph. Illinois has an action limit of 10ppm, while Virginia follows the limits outlined in the monograph. The irony of setting limits based on two different standards, however, is that the limits are the same between the standards. The AHP Monograph follows USP <467> and ICH Q3C requirements for Class 1, 2, and 3 solvents.

Extraction Solvents

CONTAMINATION SYMPTOMS:

Ethanol
- Coma & death

Butane
- Central nervous system (CNS)
- Cardiac system
- Severe brain damage
- Fetal abnormalities

Propane
- Rapid heartbeat
- Dizziness
- Headache

Symptoms more severe in children, elderly, & individuals with compromised immune systems

The classification of different solvents is based on their known toxicity, with Class 1 solvents being known carcinogens, toxic substances, and environmental hazards. These should never be used in the production of medicine and oftentimes have lower action limits than other substances. Table 8 identifies the states that require testing for Class 1 solvents. Where a state is listed twice — for example, Michigan and Missouri — the lower limit is set for inhalable products while the higher limit is for other product types.

Residual Solvent Testing Requirements	USP <467> (Class)	State
1,2-dichloroethane	5ppm (1)	DE, PA, WA, VA, RI, OH, ND, MI, MO
	1ppm	CA, ME
	2ppm	FL, MI, MO
	500ppm	MI, MO, NH
Benzene	2ppm (1)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND, OR, AZ, MI, MO, SD, NM, CO, OK, MT, DC, MD, MS
	1ppm	CA, ME, FL, MI, MO, SD, HI, LA, AK, VT

TABLE 8: STATES REQUIRING CLASS 1 SOLVENT TESTING

Class 2 solvents should be used in a limited capacity as they have potential neurotoxicity and may also be carcinogenic. These are sometimes used as co-solvents during extraction procedures or may be contaminants in what should be a pure solvent, whether gas or liquid. Numerous states are in agreement with using the limits identified in USP <467>; however, some states have also elected to set their own action limits. In addition, some states have placed limitations on the types of solvents that are permissible for use, generally requiring solvents to be at least 99% pure or listed as food grade.

Residual Solvent Testing Requirements	USP <467> (Class)	State
Acetonitrile	410ppm (2)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND, OR, CA, ME, AZ, MI, MO
	60ppm	FL, MI, MO
Chlorobenzene	360ppm (2)	DE, PA, WA, VA, OH, ND
Chloroform	60ppm (2)	DE, PA, VA, MA, OH, ND, AZ, MI, MO, MS
	1ppm	CA, ME
	2ppm	FL, MI, MO, MT
Cyclohexane	3880ppm (2)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND, OR, MT
1,2-Dimethoxyethane	100ppm (2)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND
N,N-Dimethylacetamide	1090ppm (2)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND
N,N-Dimethylformamide	880ppm (2)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND
1,4-Dioxane	380ppm (2)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND, OR
2-Ethoxyethanol	160ppm (2)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND, OR
Ethylene glycol	620ppm (2)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND, OR
Formamide	220ppm (2)	DE, PA, WA, VA, MA, OH, ND
Hexane	290ppm (2)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND, OR, CA, ME, AZ, MI, MO, SD, MT, DC, MD, MN, MS
	250ppm	FL
	50ppm	MI, MO, SD
	60ppm	CO, OK
	10ppm	HI, LA, AK, VT
Methanol	3000ppm (2)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND, OR, CA, ME, AZ, MI, MO, SD, NM, MT, MS
	250ppm	FL, MI, MO, SD
	600ppm	CO, OK
2-Methoxyethanol	50ppm (2)	DE, PA, WA, VA, MA, OH, ND
Methylbutylketone	50ppm (2)	DE, PA, WA, VA, MA, RI, OH, ND

Methylcyclohexane	1180ppm (2)	DE, PA, WA, VA, MA, RI, OH, ND
Methylene Chloride	600ppm (2)	DE, PA, WA, VA, MI, MO
	1ppm	CA, ME
	125ppm	FL, MI, MO
Nitromethane	50ppm (2)	DE, PA, WA, VA, MA, RI, OH, ND
Pyridine	200ppm (2)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND
Sulfolane	160ppm (2)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND
Tetrahydrofuran	720ppm (2)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND, OR
Tetralin	100ppm (2)	DE, PA, WA, VA, MA, RI, OH, ND
Toluene	890ppm (2)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND, OR, CA, ME, AZ, MI, MO, SD, NM, MT, DC, MD, MS
	150ppm	FL, SD
	180ppm	CO, OK
	1ppm	HI, LA, AK, VT
Total xylenes (o, m, p)	2170ppm (2)	DE, PA, WA, VA, MA, AR, UT, RI, OH, ND, OR, CA, ME, AZ, MI, MO, NM, MT, DC, MD, MS
	150ppm	FL, MI, MO, SD
	430ppm	CO, OK
	1ppm	LA, AK, VT
Trichloroethylene	80ppm (2)	DE, PA, WA, VA, MA, RI, MI, MO
	25ppm	FL, MI, MO
	1ppm	CA, ME

TABLE 9: STATES REQUIRING TESTING FOR CLASS 2 SOLVENTS

Class 3 solvents have a low potential toxicity and each solvent listed by USP <467> has a limit of 5000ppm across the board (see Table 10). Like Class 2 solvents, though, states have elected to set different limits on inhalable vs. non-inhalable products and some have elected to set different limits altogether on only a select number of solvents.

Residual Solvent Testing Requirements	USP <467> (Class)	State
Acetic Acid	5000ppm (3)	DE, PA, WA, VA, MA
Acetone	5000ppm (3)	DE, PA, WA, VA, MA, AR, UT, RI, OR, CA, ME, MI, MO, SD, NM, OK, MT
	750ppm	FL, MI, MO, SD, MS
	1000ppm	AZ, CO
Anisole	5000ppm (3)	DE, PA, WA, VA, MA
1-Butanol	5000ppm (3)	DE, PA, WA, VA, MA, AR, UT, RI
2-Butanol	5000ppm (3)	DE, PA, WA, VA, AR, UT, RI, OR
Butyl acetate	5000ppm (3)	DE, PA, WA, VA
Tert-butylmethyl ether	5000ppm (3)	DE, PA, WA, VA
Cumene	5000ppm (3)	DE, PA, WA, VA, OH
	70ppm	MA, AR, UT, RI, ND, OR
Dimethyl sulfoxide (DMSO)	5000ppm (3)	DE, PA, WA, VA, MA, AR, UT, RI
	500ppm	NH
Ethanol	5000ppm (3)	DE, PA, WA, VA, MA, AR, UT, RI, OH, CA, ME, FL, AZ, MI, MO, NM, OK, DC, MD, LA
	1000ppm	MI, MO, SD, CO, MS

Ethyl acetate	5000ppm (3)	DE, PA, WA, VA, MA, AR, UT, RI, OR, CA, ME, AZ, MI, MO, SD, MT
	400ppm	FL, MI, MO, SD, MS
	1000ppm	CO, OK
Ethyl formate	5000ppm (3)	DE, PA, WA, VA, MA
Ethyl ether	5000ppm (3)	DE, PA, WA, VA, MA, AR, UT, RI, OR, CA, ME, FL, AZ, MI, MO
	500ppm	MI, MO
Formic acid	5000ppm (3)	DE, PA, WA, VA, MA
Heptane	5000ppm (3)	DE, PA, WA, VA, MA, AR, UT, RI, OH, OR, CA, ME, FL, AZ, MI, MO, SD, NM, MT, DC, MD
	500ppm	MI, MO, SD, HI, LA, AK, VT, NV, MS
	1000ppm	CO, OK
Isobutyl acetate	5000ppm (3)	DE, PA, WA, VA, MA
Isopropyl acetate	5000ppm (3)	DE, PA, WA, VA, MA, AR, UT, RI, OR, AZ
Methyl acetate	5000ppm (3)	DE, PA, WA, VA, MA
3-Methyl-1-butanol	5000ppm (3)	DE, PA, WA, VA, MA
Methylethyl ketone	5000ppm (3)	DE, PA, WA, VA, MA, AR, UT, RI
2-Methyl-1-propanol	5000ppm (3)	DE, PA, WA, VA, MA, RI
Pentane	5000ppm (3)	DE, PA, WA, VA, MA, AR, UT, RI, OR, CA, ME, AZ, MI, MO, SD, NM, MT
	750ppm	FL, MI, MO, SD
	1000ppm	CO, OK
	3000ppm	MN
1-Pentanol	5000ppm (3)	DE, PA, WA, VA, MA, AR, UT, RI
1-Propanol	5000ppm (3)	DE, PA, WA, VA, MA, AR, UT, RI
2-Propanol	5000ppm (3)	DE, PA, WA, VA, MA, AR, UT, RI, OR, AZ, MT
Propyl acetate	5000ppm (3)	DE, PA, WA, VA, MA, RI

TABLE 10: STATES REQUIRING TESTING FOR CLASS 3 SOLVENTS

These already-established lists are a great start for states looking to regulate residual solvents, but what they do not cover are solvents that have been commonly used in cannabis extractions, most notably butane. Butane and other hydrocarbons are not identified in USP <467>, though they are cheap and readily available solvents that work well for extracting cannabinoids from the flowers. One large issue with hydrocarbon extraction is its high flammability and explosive potential.

Scores of news stories and videos of explosions, both residential and commercial, have caused regulators to evaluate hydrocarbon extraction safety and implement regulatory changes. While some states have opted to ban the use of hydrocarbons for extraction, the most predominant change is requiring all extraction equipment to be closed-loop and UL-listed or approved by a mechanical engineer. States are also now often requiring any extraction equipment that is operated at high pressures to be in an explosion-proof room with additional room air monitoring and fire suppression, both of which are important not only for product safety but also employee safety.

For regulators, establishing residual solvent testing requirements that protect patients as well as employees is critical. The compounds identified in USP <467> are a comprehensive list that protects patients; however, this list does not address the issue of hydrocarbon extraction or the use of other residual solvents like isopropyl alcohol, oftentimes used as a cleaning agent. Regulators wishing to establish sound residual solvent testing requirements should consider utilizing both the USP <467> and adding additional solvents of concern to it.

As evidenced by the vaping crisis of 2019 and current and past vape product recalls, states must also revise their regulations about the types of substances that can be added to concentrates. Vitamin E acetate has been banned in some states and others now require testing for it. However, a rising issue is that of terpenes that are not suitable for inhalation being added back into concentrates. States will need to regulate what is permissible for use and institute testing regulations around it to protect consumers.

Residual Solvent Testing Requirements	Additional Solvents	State
Butane	5000ppm	WA, AR, UT, RI, OH, ND, OR, CA, ME, FL, AZ, MI, MO, SD, NM, MT, DC, MD, MS
	1ppm	MA
	500ppm	NV
	800ppm	MI, MO, SD, HI, LA, AK, VT
	1000ppm	CO, OK
1,2-Dichloroethene	1870ppm	MA, ND
Dichloromethane	600ppm	WA, MA, AR, UT, RI, OH, ND, OR, AZ, MT, MS
2,2-Dimethylbutane	290ppm	AR, UT, RI
2,3-Dimethylbutane	290ppm	AR, UT, RI
Ethylene oxide	50ppm	AR, UT, RI, OH, ND, OR, MI, MO
	1ppm	CA, ME
	5ppm	FL, MI, MO
	500ppm	NH
Isopropyl alcohol	5000ppm	WA, CA, ME, MI, MO, SD, NM
	500ppm	FL, MI, MO, SD
	1000ppm	CO, OK
2-Methylbutane	5000ppm	AR, UT, RI
Methylisobutyl ketone	5000ppm	MA
	4500ppm	ND
2-Methylpentane	290ppm	AR, UT, RI
3-Methylpentane	290ppm	AR, UT, RI
Methylpropane	5000ppm	AR, UT, RI, NM
N-Methylpyrrolidone	530ppm	MA, RI, OH, ND
Propane	5000ppm	WA, AR, UT, RI, OH, ND, OR, CA, ME, FL, AZ, MI, MO, SD, NM, MT, DC, MD
	1ppm	MA
	500ppm	NV
	1000ppm	CO, OK
	2100ppm	MI, MO, SD
Vitamin E Acetate	100ppm	MI
	50ppm	SD
	290ppm	SD
	Screen	MA

TABLE 11: ADDITIONAL SOLVENTS STATES REQUIRE TESTING

HEAVY METALS TESTING

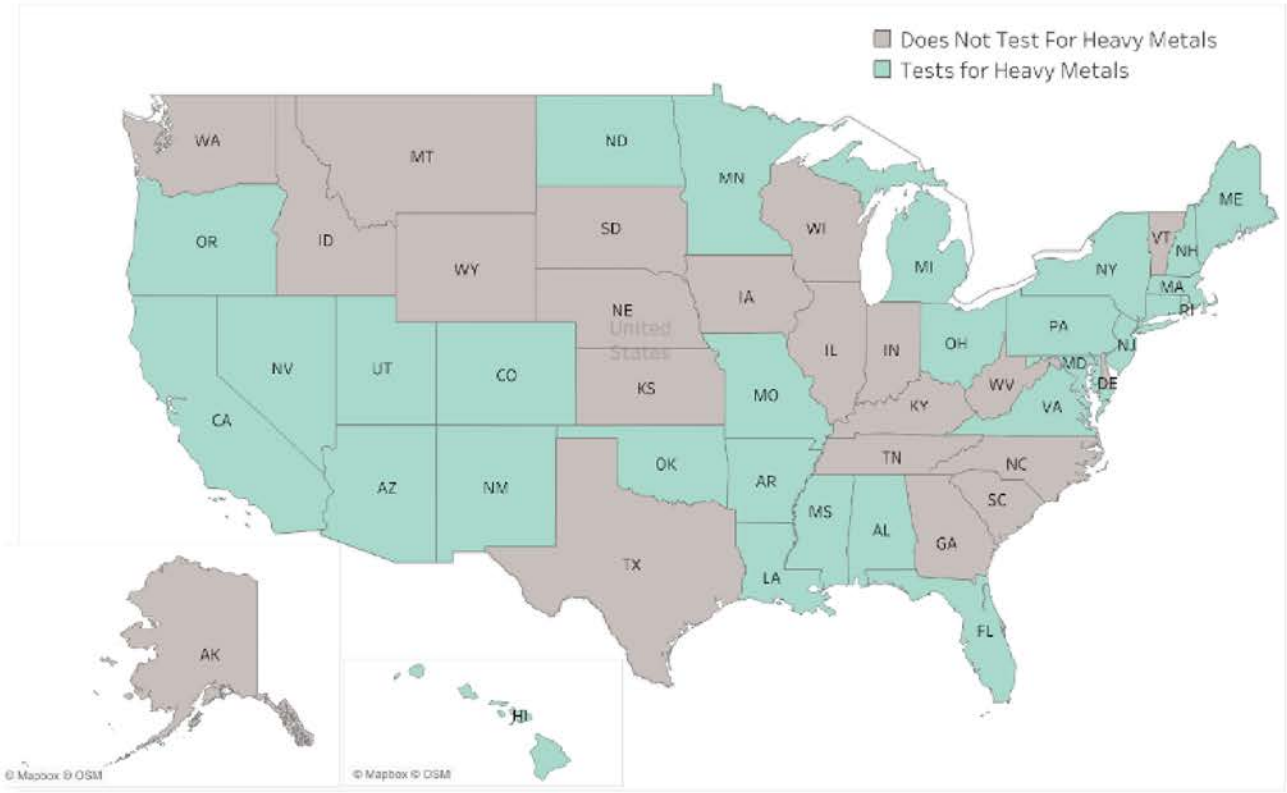


FIGURE 11: STATES THAT REQUIRE HEAVY METALS TESTING

Heavy metals testing is required by 30 of the 42 states and territories that permit cannabis. Heavy metals are a problem for cannabis plants and products because the plant itself is a bioaccumulator of heavy metals, meaning it can uptake metals from the soil the plant is growing in and then accumulate in its leaves and flowers. Cannabis vaping cartridges also carry a risk of imparting metals into cannabis extracts because some components of the cartridges may leach metals into the concentrates, particularly if they are stored for too long. Unlike pesticides and residual solvents, most states agree that the four main metals to be tested for should be arsenic, cadmium, lead, and mercury, although Maryland, Michigan, Missouri, and Washington, DC require some level of testing for up to seven different metals including chromium, barium, silver, and nickel.

Arkansas, California, Colorado, Florida, Maine, Maryland, Massachusetts, Michigan, Missouri, Oklahoma, Rhode Island, and South Dakota follow USP recommendations and many separate these limits by product type for oral (edibles, tinctures, etc.) or inhaled (flowers, concentrates) consumption.

Heavy Metal	USP <232> (Oral PDE)	USP <232> (Parenteral PDE)	USP <232> (Inhalation PDE)
Arsenic (As)	1.5ppm	1.5ppm	0.2ppm
Cadmium (Cd)	0.5ppm	0.2ppm	0.2ppm
Lead (Pb)	0.5ppm	0.5ppm	0.5ppm
Mercury (Hg)	3ppm	0.3ppm	0.1ppm

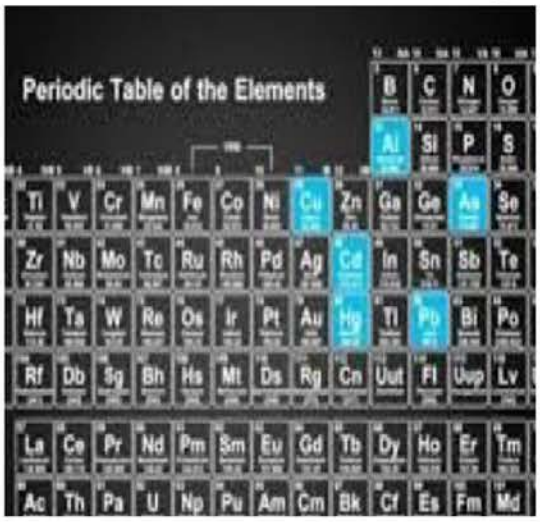
TABLE 12: USP <232> HEAVY METALS

As with the other test types, heavy metals testing requirements across the states do not consistently follow a single standard. Guam, Hawaii, Montana, Washington, Louisiana, Vermont, and Virginia all follow the AHP Cannabis Monograph. As daily dose is challenging to interpret using a singular test result with an actionable limit, many states simply list the action limit as parts per million (ppm) or parts per billion (ppb) rather than by daily exposure limit.

Heavy Metal	AHP Monograph
Arsenic (As)	10ug/daily dose
Cadmium (Cd)	4.1ug/daily dose
Lead (Pb)	6ug/daily dose
Mercury (Hg)	2.0ug/daily dose

TABLE 13: AHP CANNABIS MONOGRAPH HEAVY METALS

Heavy Metals



CONTAMINATION SYMPTOMS:

Interrupt cellular functions causing:

- cell cycle modulation
- carcinogenesis
- apoptosis (cell death)

Brain Neuron development & growth

- Lower intelligence
- Learning disabilities
- Reduced brain development

Symptoms more severe in children, elderly, & individuals with compromised immune systems

The remaining states comprise a varying set of limits, sometimes based on product type (Colorado and Oklahoma), and sometimes with differing units (Connecticut and Ohio).

Heavy Metal	ND, PA	AZ, MS	SD, DC, MD, MI	ME	CO, OK, MA, RI	IA, MN	CO, OK	CT, OH	NM, MT, NV, UT	NH
Arsenic (As)	0.4ppm	0.4ppm	0.4ppm	1ppm	1.5ppm	1.5ppm	3ppm	0.14 ug/kg BW/day	2.0ppm	4.2ppm
Cadmium (Cd)	0.3ppm	0.4ppm	0.4ppm	5ppm	0.5ppm	0.3ppm	3ppm	0.09 ug/kg BW/day	0.8ppm	2.7ppm
Lead (Pb)	1.0ppm	1.0ppm	1.0ppm	10ppm	1ppm	1.0ppm	10ppm	0.29 ug/kg BW/day	1.2ppm	8.7ppm
Mercury (Hg)	0.2ppm	1.2ppm	0.2ppm	1ppm	1.5ppm	0.5ppm	1ppm	0.29 ug/kg BW/day	0.4ppm	8.7ppm

TABLE 14: STATE HEAVY METALS LIMITS

Heavy metals pose a significant health risk to medical cannabis patients and adult-use consumers alike — even at very small doses — and regulators must take steps to ensure that testing is not only mandatory but must also establish limits that will protect everyone. The USP <232> limits are based on product type, and the limits are more stringent than the AHP Monograph and similar enough to the limits from the other states to set a universal standard following USP. Testing of the actual aerosol produced by vaporizers should also be required, as it has been shown that concentrates may pass heavy metals testing before vaporization but fail after combustion.[38]

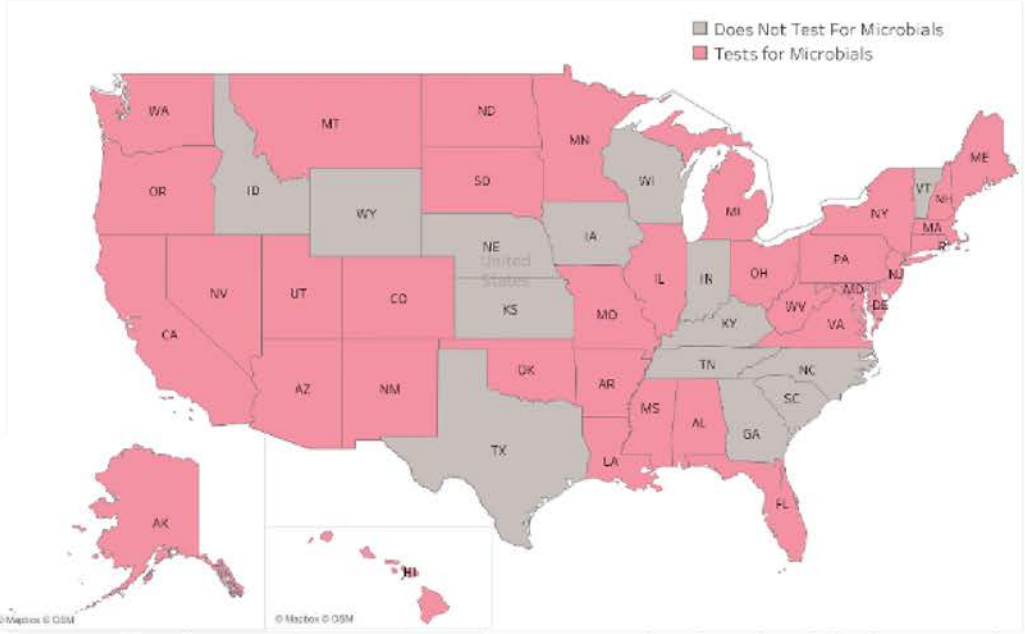


FIGURE 12: STATES THAT REQUIRE MICROBIOLOGICAL TESTING

Microbiological testing is required by 38 states, making it the most required contaminant test for cannabis. Microbiological contaminants pose numerous health threats to humans that are introduced through both handling and consuming cannabis. Contaminants can be both airborne and present on surfaces, and because they are ubiquitous, the levels that may cause harm must be determined to adequately protect everyone.

While most states require microbiological testing, the types of microbials tested for and the amounts tested, vary greatly from state to state. The testing discrepencies in Aspergillus, for example, are shown below in Figure 13.

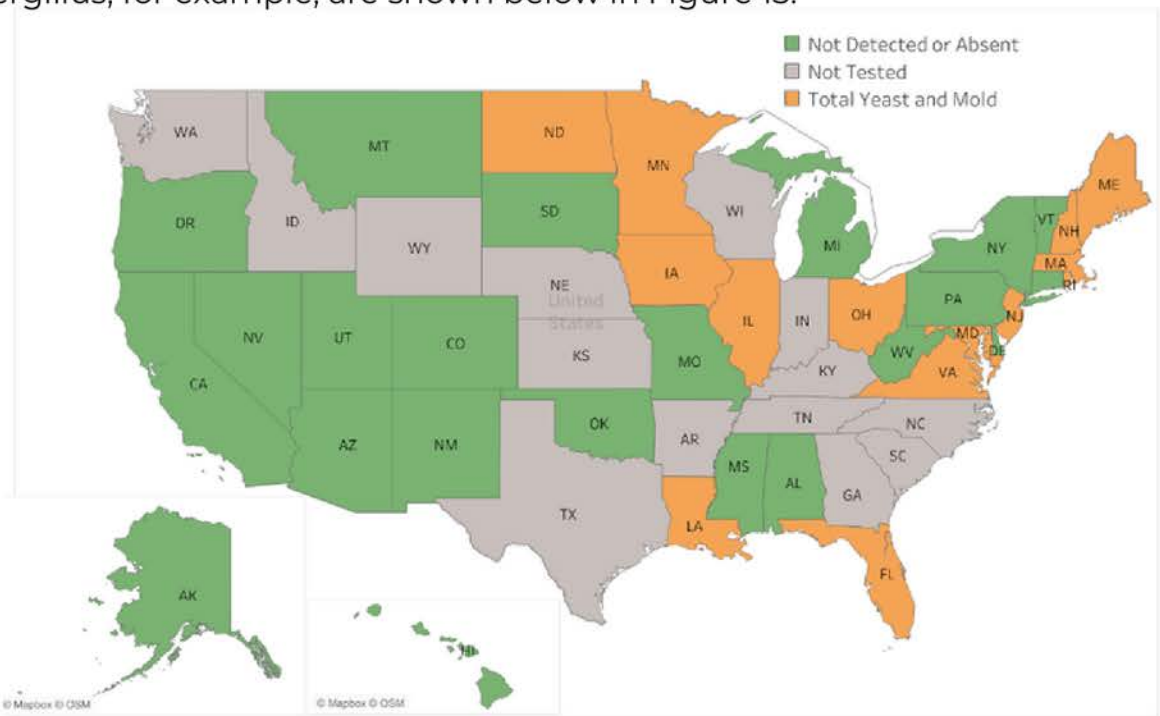


FIGURE 13: STATE BY STATE ASPERGILLUS TESTING

States in Green Require that Aspergillus is Not Detected. Those in Orange look at Total Yeast and Mold Count States in Gray do not test or are N/A.

As with the other testing requirements, there are a number of different standards that states have chosen to follow. Thirteen states require testing that follows the AHP Cannabis Monograph (Table 15), which separates items by product type (unprocessed/processed materials and extracts) and establishes action limits for each. South Dakota, Guam, and Hawaii add additional requirements for the testing of four different Aspergillus species, as numerous species can support the growth of Aflatoxins[39].

Microbial Testing Requirements	AHP Monograph (Unprocessed/ Processed Materials)	ME, MA, NH, ND, DE, PA, OH	SD, GU, HI	AHP Monograph (Extracts)	IL, NH, ND, ME, MA, RI, MD, DE, PA, OH
Shiga-toxin producing E. Coli	<1 CFU/g	<1 CFU/g	<1 CFU/g	<1 CFU/g	<1 CFU/g
Salmonella spp.	<1 CFU/g	<1 CFU/g	<1 CFU/g	<1 CFU/g	<1 CFU/g
Aspergillus fumigatus			<1 CFU/g		
Aspergillus flavus			<1 CFU/g		
Aspergillus niger			<1 CFU/g		
Aspergillus terreus			<1 CFU/g		
Total Yeast and Mold	10^4 CFU/g	<10^4 CFU/g	<10^4 CFU/g	10^3 CFU/g	<10^3 CFU/g
Total Aerobic Microbials	10^5 CFU/g	<10^5 CFU/g	<10^5 CFU/g	10^4 CFU/g	<10^4 CFU/g
Bile-tolerant gram-negative bacteria	10^3 CFU/g	<10^3 CFU/g	<10^3 CFU/g	10^2 CFU/g	<10^2 CFU/g
Total coliform	10^3 CFU/g	<10^3 CFU/g	10^3 CFU/g	10^2 CFU/g	<10^2 CFU/g
Total Enterobacteriaceae		<10^3 CFU/g			

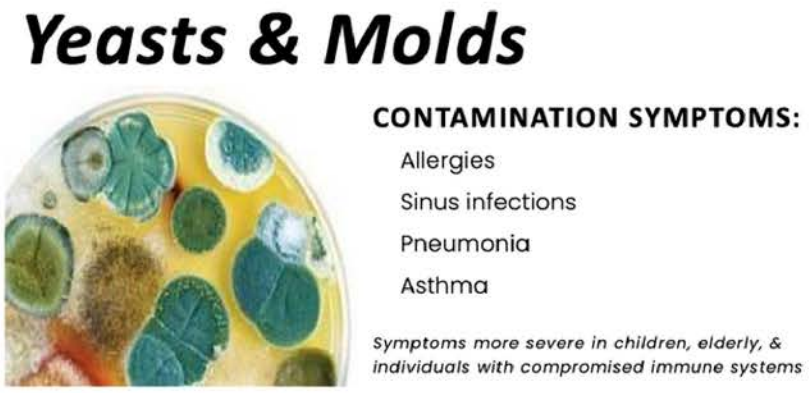
TABLE 15: AHP CANNABIS MONOGRAPH TESTING REQUIREMENTS

Iowa, Utah, Connecticut, Virginia, and Washington, DC require testing of many portions of USP <1111>, which separates products into seven different categories. The five that are most applicable to cannabis are outlined in Table 16. Connecticut also separately requires raw flower material to meet the specifications of USP <2023>.

Microbial Testing Requirements	USP <1111> Nonaqueous	USP <1111> Aqueous	USP <1111> Oromucosal	USP <1111> Transdermal	USP <1111> Inhalation
Shiga-toxin producing E. Coli	<1 CFU/g	<1 CFU/g			
Total Yeast and Mold	10^2 CFU/g	10^1 CFU/g	10^1 CFU/g	10^1 CFU/g	10^1 CFU/g
Total Aerobic Microbials	10^3 CFU/g	10^2 CFU/g	10^2 CFU/g	10^2 CFU/g	10^2 CFU/g
Staphylococcus aureus			<1 CFU/g	<1 CFU/g	<1 CFU/g
Pseudomonas aeruginosa			<1 CFU/g	<1 CFU/g	<1 CFU/g
Bile-tolerant gram-negative bacteria					<1 CFU/g

TABLE 16: USP <1111> MICROBIOLOGICAL TESTING REQUIREMENTS

States such as California and Nevada separate out their testing requirements by product type, while limiting the microbials to be tested for to E. Coli, Salmonella, and Aspergillus species with additional requirements including Total Yeast and Mold, Total Coliforms, and Total Enterobacteriaceae.



Microbial Testing Requirements	AK, CA, MO, AZ, NM	NV, FL, OK, MI, UT	LA, WA, NV, CA, MT, CO
Shiga-toxin producing E. Coli	<1CFU/g	<1 CFU/g	<1 CFU/g
Salmonella spp.	<1CFU/g	<1 CFU/g	<1 CFU/g
Aspergillus fumigatus	<1CFU/g	<1 CFU/g	
Aspergillus flavus	<1CFU/g	<1 CFU/g	
Aspergillus niger	<1CFU/g	<1 CFU/g	
Aspergillus terreus	<1CFU/g	<1 CFU/g	
Total Yeast and Mold		<10^4 CFU/g	<10^3 CFU/g
Total coliform		<10^3 CFU/g	
Total Enterobacteriaceae		<10^3 CFU/g	

TABLE 17: VARIOUS STATE TESTING REQUIREMENTS

Minnesota and Vermont elected to choose different limits and different species, with no consistency based on a specific standard.

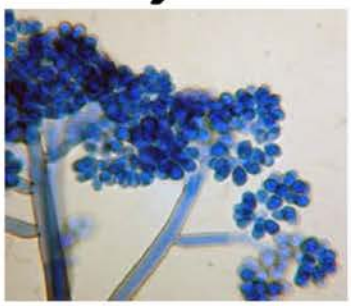
Microbial Testing Requirements	Minnesota	Vermont
Shiga-toxin producing E. Coli	<7 CFU/g	<200 CFU/g
Salmonella spp.	<1 CFU/g	<200 CFU/g
Aspergillus flavus		<200 CFU/g
Aspergillus niger		<200 CFU/g
Aspergillus fumigatus		<200 CFU/g
Total Yeast and Mold	<10^3 CFU/g	
Total Aerobic Microbials	<10^5 CFU/g	
Bile-tolerant gram-negative bacteria	<150 CFU/g	

TABLE 18: MINNESOTA AND VERMONT MICROBIAL TESTING REQUIREMENTS

The one consistency amongst the various microbial testing limits is the units, reported as Colony Forming Units per gram or milliliter (CFU/g or CFU/mL). The AHP Cannabis Monograph, USP, and American Herbal Products Association (AHPA) put forth recommendations on microbiological testing for pharmaceutical products, nutritional and dietary supplements, and botanical products. Cannabis fits into each of these categories and for regulators it presents issues around which standard should be followed.

The AHP Monograph sets reasonable standards for unprocessed and processed flowers and extracts but fails to address edibles, tinctures, transdermal, and topical products. For those products which are not defined, standards should follow at a minimum the appropriate chapter from the USP.

Botrytis cinerea (gray mold)



CONTAMINATION SYMPTOMS:

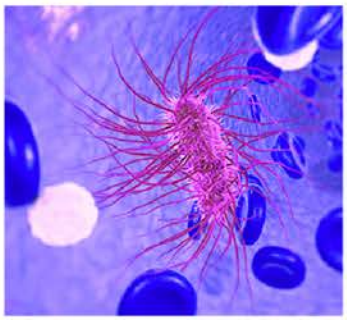
Sinus & lung infections

Allergies

Lung inflammation

Symptoms more severe in children, elderly, & individuals with compromised immune systems

Escherichia coli (E. Coli)



CONTAMINATION SYMPTOMS:

Abdominal cramping
Diarrhea
Fever
Vomiting
Risk of seizure
Coma
Stroke
Haemolyticuraemic syndrome (HUS)

Symptoms more severe in children, elderly, & individuals with compromised immune systems

Aspergillus Species

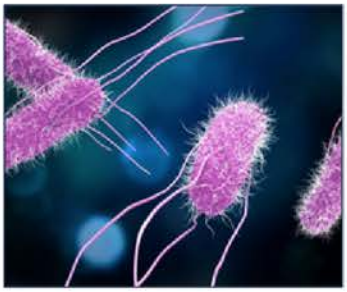
CONTAMINATION SYMPTOMS:

Sinus & lung infections

Chronic pulmonary aspergillosis (CPA)

Symptoms more severe in children, elderly, & individuals with compromised immune systems

Salmonella Species



CONTAMINATION SYMPTOMS:

Gastrointestinal discomfort

Cramps

Diarrhea

Symptoms more severe in children, elderly, & individuals with compromised immune systems

AFLATOXIN TESTING

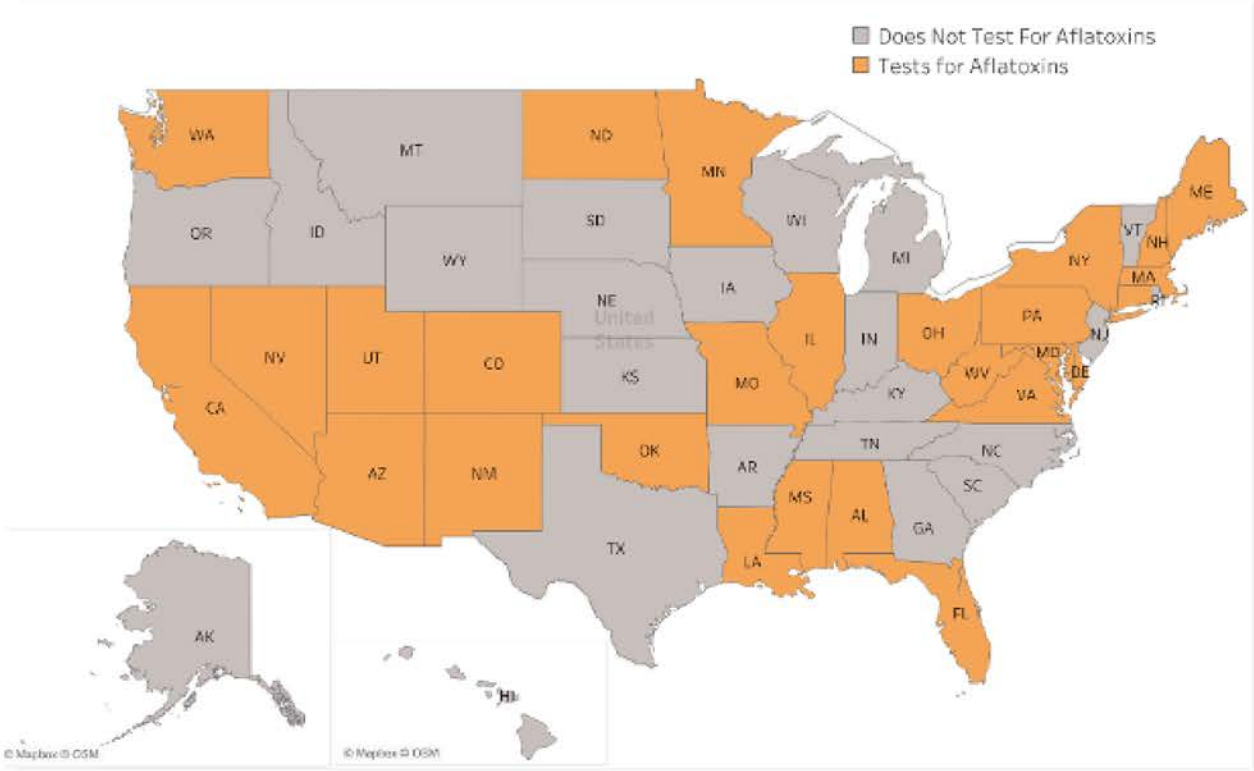
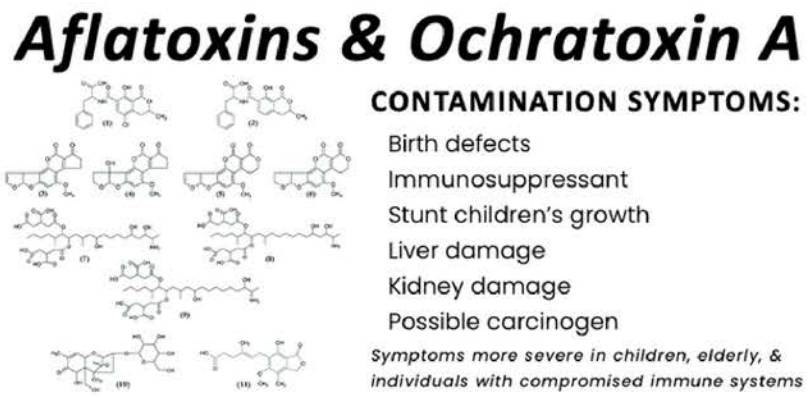


FIGURE 14: STATES THAT REQUIRE AFLATOXIN TESTING

Aflatoxin testing is becoming increasingly required by states, with 28 requiring it at the time of writing. Aflatoxins come from certain species of Aspergillus, which must be tested for by some states. Aflatoxins, also called mycotoxins, are broken down into 5 primary species — Aflatoxin B1, B2, G1, G2, and Ochratoxin A. They are carcinogenic and toxic and arise when products that have an overly high moisture content are stored for long periods of time, allowing the Aspergillus to begin producing aflatoxins.

Of the 28 states that require testing for aflatoxins, 15 require that tests evaluate Ochratoxin A and a sum of the 4 aflatoxins (Table 19). A smaller number (9) of states require testing for each of the aflatoxins and Ochratoxin A individually, while Minnesota and Pennsylvania have set separate testing requirements. As noted in other tests, the units for each reporting limit can be listed differently, despite being the same (1ug/kg = 1ppb).



Aflatoxin Testing Requirements	AZ, CA, ME, MT, NV, NH, ND, OH, NM, UT, WA, CO, MO, OK, SD	CT, GU, HI, IL, VA, FL, LA, MD, MA, MS	MN	PA
Ochratoxin A	<20ug/kg	<20ug/kg		5ppb
Aflatoxin (B1, B2, G1, G2)	<20ug/kg		20ppb	20ppb
Aflatoxin B1		<20ug/kg	5ppb	5ppb
Aflatoxin B2		<20ug/kg		5ppb
Aflatoxin G1		<20ug/kg		5ppb
Aflatoxin G2		<20ug/kg		5ppb

TABLE 19: STATE AFLATOXIN TESTING SUMMARY

For regulators this may seem like an easier contaminant test to manage, with a smaller list of species to test for and a smaller set of potential limits. However, states must be aware when utilizing regulations that have been written for other states that errors may exist. For example, Figure 15 is a screenshot image of section 21a-408-72 of Connecticut's Regulations for the Palliative Use of Medical Marijuana, incorrectly listing Aflatoxin O1 and O2. The aflatoxins were named because of the color wavelength at which they are detected, brown and green, and this error was likely a transcription error that was not identified. This error was transcribed into other state regulations, and though they have since been edited to reflect the correct species, the error persists in Connecticut.

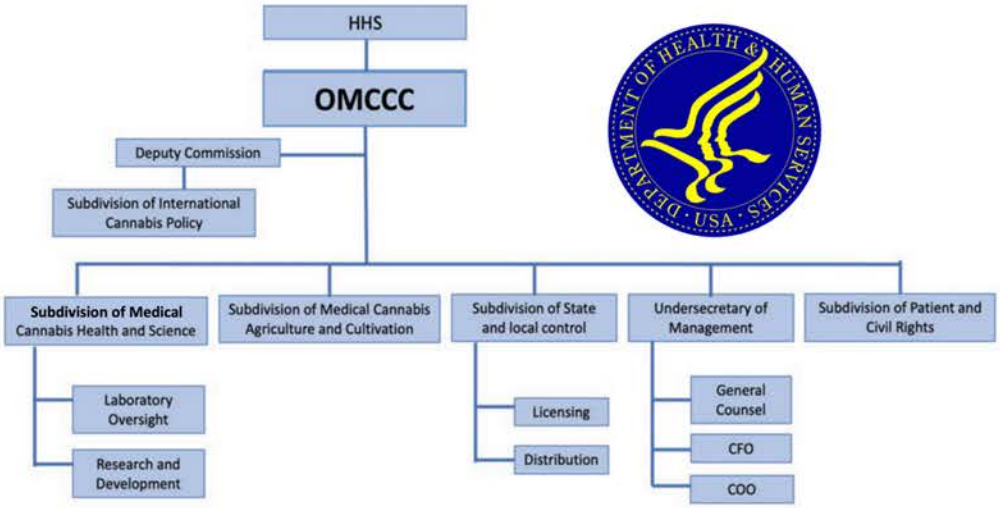
Test	Specification
Alfatoxin B1	<20 uG/KG of Substance
Alfatoxin B2	<20 uG/KG of Substance
Alfatoxin O1	<20 uG/KG of Substance
Alfatoxin O2	<20 uG/KG of Substance
Ochratoxin A	<20 uG/KG of Substance

FIGURE 15: CONNECTICUT STATUTE SECTION 21A-408-72

With cultivators and processors expressing concerns around the cost of testing their batches, some states have begun to implement new requirements for aflatoxin testing. Colorado requires that a batch be screen tested for Ochratoxin A and then screen tested again for the presence of Aflatoxins B1, B2, G1, and G2. Should one of the results come back positive, the sample must then be tested and quantified to determine if it will pass or fail. Screen testing is a cheaper alternative than utilizing the more expensive instrumentation needed to quantify the aflatoxins and should be considered as an option by regulators.

ASA'S RECOMMENDATIONS

1. **Call on Congress to create a National Office of Medical Cannabis and Cannabinoid Control (OMCCC):** Establishment of a centralized regulatory body at the federal level, such as the OMCCC would work collaboratively with state governments in developing and implementing standardized testing programs. This office would provide guidance, resources, and oversight to ensure consistent and effective regulations across the country. (see Appendix IV)

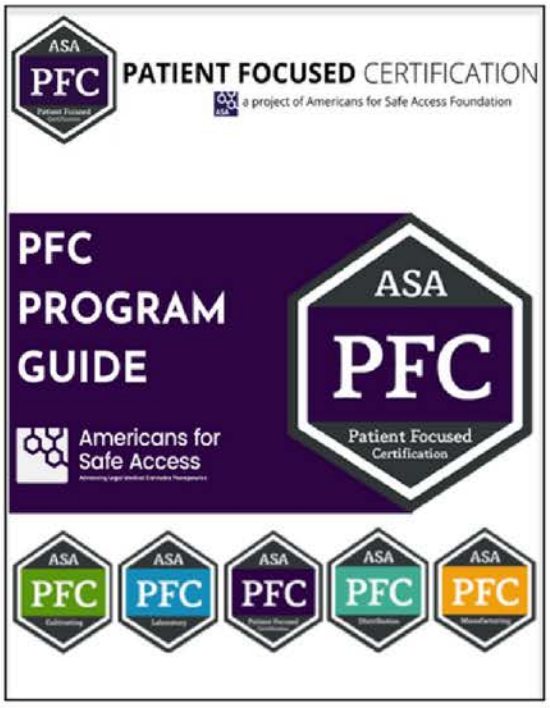


2. **Implement Upstream Product Safety Inspections and Certifications:** Introduce inspections and certifications throughout the cannabis supply chain, from cultivation to manufacturing and distribution. These inspections would focus on ensuring adherence to quality control standards, proper handling of cannabis products, and the implementation of good agricultural and manufacturing practices. By addressing potential contamination risks early on, patient health can be better protected. Projects like ASA's Patient Focused Certification Program offer these services to businesses and regulators.

ASA PFC Patient Focused Certification
PATIENT FOCUSED CERTIFICATION
a project of Americans for Safe Access Foundation
patientfocusedcertification.org

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

AHP
AMERICAN HERBAL PHARMACOPOEIA®



3. Adoption of Comprehensive Testing Program Protocols by State, including the following:

a. Accreditation and Certification of Testing Laboratories: Implement accreditation programs for testing laboratories, ensuring they meet strict quality standards and demonstrate proficiency in conducting accurate and reliable tests. This will instill confidence in the testing process and the results obtained.

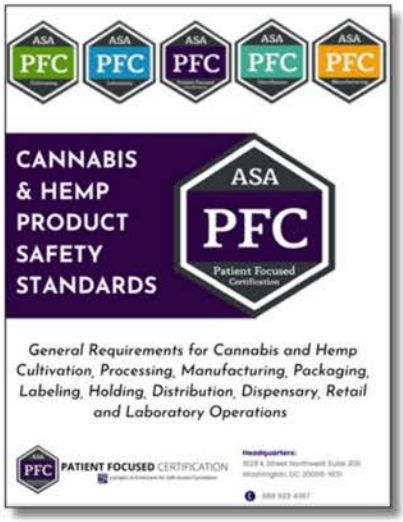
b. Transparency and Consumer Education: Require the provision of clear and standardized information to consumers through the use of Certificates of Analysis (CoA) or similar documentation. CoAs should include comprehensive details about the cannabinoid and terpene profiles, as well as the presence of contaminants, allowing consumers to make informed decisions.

c. Regulatory Oversight and Enforcement: Strengthen regulatory oversight and enforcement mechanisms to ensure compliance with testing program protocols. This includes regular inspections of testing laboratories, product manufacturers, and dispensaries to verify adherence to regulations and standards.

d. Create State-wide Proficiency Testing for Cannabis Testing Laboratories: States should create Proficiency testing programs to evaluate the performance of individual laboratories for tests or measurements and to monitor laboratories' ongoing performance.

e. Expand Access to Independent Cannabis Testing Laboratories: Allow testing laboratories to test products submitted by patients. This can benefit patients, for example, by allowing patients to validate the safety and efficacy of their products after purchase and subsequent environmental degradation. Such statutes would also facilitate research from law enforcement, universities, and secret shoppers.

f. Adopt ASA's PFC Standards in regulations for Supply Chain: Visit www.safeaccessnow.org/pfcstandards to learn more.



By implementing these recommendations, state cannabis testing programs can be enhanced, leading to improved patient health outcomes, increased consumer confidence, and the establishment of a more robust and standardized regulatory framework for the cannabis industry.

CONCLUSION

This report highlights the multitude of testing inconsistencies of cannabis products between states, including differences in compounds and species to be tested for, limits for those substances, methodologies, and reporting units. These profound differences of testing requirements between states creates huge problems for laboratories and multi-state operators, which are required to adhere to different standards depending on where they are operating.

Most states at a minimum require potency testing; however, states are failing patients and consumers by not requiring the reporting of additional cannabinoids besides the five primary ones and by not consistently requiring homogeneity testing for edible products or terpene testing for inhalable products. One reason many of these regulations only require five cannabinoid tests is that they were written when these were the only standards available for testing. Today, there are dozens of commercially available cannabinoid standards that should be utilized by laboratories and operators in order to convey cannabinoid information to patients, consumers, researchers, and healthcare professionals. Terpenes are an important aspect of a product's potency and should be tested for and reported to end users as such.

Pesticides are a health hazard for workers and consumers and should be regulated sensibly. Because they are not approved for cannabis and have limited approval on hemp, and because there is a lack of scientific research on the effects of pesticide vaporization and inhalation, states should look to adopt more stringent regulations with lower action limits until the health impacts can be fully understood. When a pesticide is consistently undetected during cannabis analysis, the state may then consider removing it from their list of required compounds to be tested for. As the science around vaporization and inhalation changes, action limits should be adjusted accordingly.

Residual solvents are a health and safety hazard as they may become volatile if overly high levels of hydrocarbons and other flammable chemicals remain in finished products. The United States Pharmacopeia outlines residual solvents that are regulated in the production of pharmaceutical products and provides a strong list to follow; however, it fails to recognize the hydrocarbons that are commonly used in cannabis extractions.

State testing requirements should include the USP requirements for Class 1, 2, and 3 solvents and add in testing requirements for hydrocarbons. Similar to the recommendations for pesticides, as laboratories identify the chemicals that are not detected in cannabis products, they can be removed from required testing lists. Additionally, as more scientific research is conducted on the health impacts of residual solvents, action limits can be adjusted.

Because of the multiple ways in which heavy metals may be imparted into cannabis products, it is important that states require testing for them. At a minimum, the four primary metals should be included in testing requirements. The USP requirements for metals testing break them down into product types and, because multiple product types could be affected by metals contamination, it is important that states follow this type of testing scheme.

Microbiological contaminants, including aflatoxins, represent a health hazard to workers who may be exposed to unsafe levels of contaminants and consumers who may inhale or ingest them. Because aflatoxins arise from Aspergillus species, it is necessary for states to require testing of them. The AHP Monograph's microbiological testing requirements for microbiological species sets a standard for flowers (unprocessed and processed) and extracts but fails to set a standard for edible, topical, and transdermal products. States should look to the AHP Monograph for flower and extract products while looking to the USP for edible, topical, and transdermal products.

Testing of cannabis products helps to prevent contaminated or adulterated products from entering the market, reducing the likelihood of a recall needing to take place, protecting patients and consumers, and promoting health equity. While there are numerous different standards that states can follow, it is essential that they begin to establish a consistent set of testing standards that can be applied across all markets. Because the cannabis marketplace is still relatively new, it is sensible to implement more robust testing requirements in the beginning, subsequently easing restrictions as more data becomes available.

APPENDIX I: ADDITIONAL TESTING TABLES

Pesticide Testing Requirements	Arizona	Michigan	Mississippi	Missouri	Oregon	Arkansas	Pennsylvania	Utah	Washington
Abamectin	0.5ppm	0.5ppm	0.5ppm	0.5ppm	0.5ppm	0.5ppm	0.5ppm	0.5ppm	0.5ppm
Acephate	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm
Acequinocyl	2.0ppm	2ppm	2ppm	2ppm	2ppm	2ppm	2ppm	2ppm	2ppm
Acetamiprid	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Aldicarb	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm
Azoxystrobin	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Bifenazate	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Bifenthrin	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Boscalid	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm
Carbaryl	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Carbofuran	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Chlormequat chloride			0.2ppm	0.2ppm					
Chlorantraniliprole	0.2ppm	0.2ppm		0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Chlorfenapyr	1.0ppm	1ppm		1ppm	1ppm	1ppm	1ppm	1ppm	1ppm
Chlorpyrifos	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Clofentezine	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Cyfluthrin	1.0ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm
Cypermethrin	1.0ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm
Daminozide	1.0ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm
DDVP (Dichlorvos)	0.1ppm	1ppm	0.1ppm	1ppm	1ppm	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Diazinon	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Dimethoate	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Ethoprophos	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Etofenprox	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm
Etoxazole	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Fenoxycarb	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Fenpyroximate	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm
Fipronil	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm
Flonicamid	1.0ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm
Fludioxonil	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm
Hexythiazox	1.0ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm

APPENDIX I: ADDITIONAL TESTING TABLES

Pesticide Testing Requirements Continued	Arizona	Michigan	Mississippi	Missouri	Oregon	Arkansas	Pennsylvania	Utah	Washington
Abamectin	0.5ppm	0.5ppm	0.5ppm	0.5ppm	0.5ppm	0.5ppm	0.5ppm	0.5ppm	0.5ppm
Acephate	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm
Acequinocyl	2.0ppm	2ppm	2ppm	2ppm	2ppm	2ppm	2ppm	2ppm	2ppm
Acetamiprid	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Aldicarb	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm
Azoxystrobin	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Bifenazate	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Bifenthrin	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Boscalid	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm
Carbaryl	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Carbofuran	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Chlormequat chloride			0.2ppm	0.2ppm					
Chlorantraniliprole	0.2ppm	0.2ppm		0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Chlorfenapyr	1.0ppm	1ppm		1ppm	1ppm	1ppm	1ppm	1ppm	1ppm
Chlorpyrifos	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Clofentezine	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Cyfluthrin	1.0ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm
Cypermethrin	1.0ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm
Daminozide	1.0ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm
DDVP (Dichlorvos)	0.1ppm	1ppm	0.1ppm	1ppm	1ppm	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Diazinon	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Dimethoate	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Ethoprophos	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Etofenprox	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm
Etoxazole	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Fenoxycarb	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm
Fenpyroximate	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm
Fipronil	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm
Flonicamid	1.0ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm
Fludioxonil	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm	0.4ppm
Hexythiazox	1.0ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm	1ppm
Imazalil	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm	0.2ppm

APPENDIX I: ADDITIONAL TESTING TABLES

Pesticide Testing Requirements	D.C.	Maryland
Abamectin	0.5ppm	0.5ppm
Acetamiprid	0.2ppm	0.2ppm
Aldicarb	0.4ppm	0.4ppm
Ancymidol	0.2ppm	0.2ppm
Azoxystrobin	0.2ppm	0.2ppm
Bifenazate	0.2ppm	0.2ppm
Bifenthrin	0.2ppm	0.2ppm
Boscalid	0.4ppm	0.4ppm
Carbaryl	0.2ppm	0.2ppm
Carbofuran	0.2ppm	0.2ppm
Chlorantraniliprole	0.2ppm	0.2ppm
Chlorpyrifos	0.2ppm	0.2ppm
Clofentezine	0.2ppm	0.2ppm
Cyfluthrin	1.0ppm	1.0ppm
Daminozide	0.1ppm	1.0ppm
DDVP (Dichlorvos)	0.1ppm	0.1ppm
Diazinon	0.2ppm	0.2ppm
Dimethoate	0.2ppm	0.2ppm
Ethephon	1.0ppm	1.0ppm
Etoxazole	0.2ppm	0.2ppm
Fenpyroximate	0.5ppm	0.5ppm
Fipronil	0.4ppm	0.4ppm
Flonicamid	1.0ppm	1.0ppm
Fludioxonil	0.4ppm	0.4ppm
Flurprimidol	0.2ppm	0.2ppm
Hexythiazox	1.0ppm	1.0ppm
Imazalil	0.2ppm	0.2ppm
Imidacloprid	0.4ppm	0.4ppm
Kresoxim Methyl	0.4ppm	0.4ppm
Malathion	0.2ppm	0.2ppm
Metalaxyl	0.2ppm	0.2ppm

Pesticide Testing Requirements	D.C.	Maryland
Methiocarb	0.2ppm	0.2ppm
Methomyl	0.4ppm	0.4ppm
Myclobutanil	0.2ppm	0.2ppm
Naled	0.5ppm	0.5ppm
Oxamyl	1.0ppm	1.0ppm
Paclobutrazol	0.4ppm	0.4ppm
Permethrin (cis + trans)	0.5ppm	0.5ppm
Phosmet	0.2ppm	0.2ppm
Piperonyl Butoxide	1.0ppm	1.0ppm
Propiconazole	0.4ppm	0.4ppm
Pyrethrins	1.0ppm	1.0ppm
Spinosad	0.2ppm	0.2ppm
Spiromesifen	0.2ppm	0.2ppm
Spirotetramat	0.2ppm	0.2ppm
Thiacloprid	0.2ppm	0.2ppm
Thiamethoxam	0.2ppm	0.2ppm
Trifloxystrobin	0.2ppm	0.2ppm

APPENDIX I: ADDITIONAL TESTING TABLES

Pesticide Testing Requirements	California (inhalation)	Florida (inhalation)	California (non- inhalation)	Florida (non- inhalation)
Abamectin	0.1ppm	0.1ppm	0.3ppm	0.3ppm
Acephate	0.1ppm	0.1ppm	5ppm	3ppm
Acequinocyl	0.1ppm	0.1ppm	4ppm	2ppm
Acetamiprid	0.1ppm	0.1ppm	5ppm	3ppm
Aldicarb	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Azoxystrobin	0.1ppm	0.1ppm	40ppm	3ppm
Bifenazate	0.1ppm	0.1ppm	5ppm	3ppm
Bifenthrin	3ppm	0.1ppm	0.5ppm	0.5ppm
Boscalid	0.1ppm	0.1ppm	10ppm	3ppm
Captan	0.7ppm	0.7ppm	5ppm	3ppm
Carbaryl	0.5ppm	0.5ppm	0.5ppm	0.5ppm
Carbofuran	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Chlormequat chloride		1ppm		3ppm
Chlorantraniliprole	10ppm	1ppm	40ppm	3ppm
Chlordane	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Chlorfenapyr	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Chlorpyrifos	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Clofentezine	0.1ppm	0.2ppm	0.5ppm	0.5ppm
Coumaphos	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Cyfluthrin	2ppm	0.5ppm	1ppm	1ppm
Cypermethrin	1ppm	0.5ppm	1ppm	1ppm
Daminozide	0.1ppm	0.1ppm	0.1ppm	0.1ppm
DDVP (Dichlorvos)	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Diazinon	0.1ppm	0.1ppm	0.2ppm	0.2ppm
Dimethoate	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Dimethomorph	2ppm	0.2ppm	20ppm	3ppm
Ethoprophos	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Etofenprox	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Etoxazole	0.1ppm	0.1ppm	1.5ppm	1.5ppm
Fenhexamid	0.1ppm	0.1ppm	10ppm	3ppm
Fenoxycarb	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Fenpyroximate	0.1ppm	0.1ppm	2ppm	2ppm
Fipronil	0.1ppm	0.1ppm	0.1ppm	0.1ppm

APPENDIX I: ADDITIONAL TESTING TABLES

Pesticide Testing Requirements Continued	California (inhalation)	Florida (inhalation)	California (non- inhalation)	Florida (non- inhalation)
Flonicamid	0.1ppm	0.1ppm	2ppm	2ppm
Fludioxonil	1ppm	0.1ppm	30ppm	3ppm
Hexythiazox	0.1ppm	0.1ppm	2ppm	2ppm
Imazalil	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Imidacloprid	5ppm	0.4ppm	3ppm	3ppm
Kresoxim Methyl	0.1ppm	0.1ppm	1ppm	1ppm
Malathion	0.5ppm	0.2ppm	5ppm	2ppm
Metalaxyl	2ppm	0.1ppm	15ppm	3ppm
Methiocarb	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Methomyl	1ppm	0.1ppm	0.1ppm	0.1ppm
Methyl Parathion	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Mevinphos	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Myclobutanil	0.1ppm	0.1ppm	9ppm	3ppm
Naled	0.1ppm	0.25ppm	0.5ppm	0.5ppm
Oxamyl	0.5ppm	0.5ppm	0.2ppm	0.5ppm
Paclobutrazol	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Pentachloronitrobenzene	0.1ppm	0.15ppm	0.2ppm	0.2ppm
Permethrin (cis + trans)	0.5ppm	0.1ppm	20ppm	1ppm
Phosmet	0.1ppm	0.1ppm	0.2ppm	0.2ppm
Piperonyl Butoxide	3ppm	3ppm	8ppm	3ppm
Prallethrin	0.1ppm	0.1ppm	0.4ppm	0.4ppm
Propiconazole	0.1ppm	0.1ppm	20ppm	1ppm
Propoxur	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Pyrethrins	0.5ppm	0.5ppm	1ppm	1ppm
Pyridaben	0.1ppm	0.2ppm	3ppm	3ppm
Spinetoram	0.1ppm	0.2ppm	3ppm	3ppm
Spinosad	0.1ppm	0.1ppm	3ppm	3ppm
Spiromesifen	0.1ppm	0.1ppm	12ppm	3ppm
Spirotetramat	0.1ppm	0.1ppm	13ppm	3ppm
Spiroxamine	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Tebuconazole	0.1ppm	0.1ppm	2ppm	1ppm
Thiacloprid	0.1ppm	0.1ppm	0.1ppm	0.1ppm
Thiamethoxam	5ppm	0.5ppm	4.5ppm	1ppm
Trifloxystrobin	0.1ppm	0.1ppm	30ppm	3ppm

APPENDIX II: REFERENCES & RESOURCES

American Herbal Products Association Recommended Microbial Limits for Botanical Ingredients
www.ahpa.org/Portals/0/PDFs/Policies/14_0206_AHPA_micro_limits_comparisons.pdf

Americans for Safe Access 2022 State of the States Report
www.safeaccessnow.org/sos22

International Council on Harmonization Q3C - Tables and List Guidance for Industry
www.fda.gov/media/71737/download

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www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/generalChapter467Current.pdf

United States Pharmacopeia Chapter <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use
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APPENDIX II: REFERENCES & RESOURCES

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APPENDIX II: REFERENCES & RESOURCES

FIGURES

TABLES

APPENDIX III: STATE REGULATIONS

State	Cannabis Authority Website
Alaska	https://www.commerce.alaska.gov/web/amco/
Arizona	https://www.azdhs.gov/licensing/marijuana/index.php
Arkansas	https://www.google.com/url?q=https://www.healthy.arkansas.gov/programs-services/topics/medical-marijuana-faqs&sa=D&source=editors&ust=1685328403368114&usg=AOvVaw2LaNJ92t9jEGQfprBTqgP8
California	https://cannabis.ca.gov/
Colorado	https://cannabis.colorado.gov/
Connecticut	https://portal.ct.gov/cannabis/?language=en_US
Delaware	https://knowthefactsmmj.com/
District of Columbia	https://abra.dc.gov/page/medical-cannabis-program
Florida	https://knowthefactsmmj.com/
Georgia	https://www.gmcc.ga.gov/
Hawaii	https://health.hawaii.gov/medicalcannabis/
Illinois	https://dph.illinois.gov/topics-services/prevention-wellness/medical-cannabis.html
Kentucky	https://medicalcannabis.ky.gov/
Louisiana	https://ldh.la.gov/page/4518
Maine	https://www.maine.gov/dafs/ocp/
Maryland	https://mmcc.maryland.gov/Pages/home.aspx
Massachusetts	https://masscannabiscontrol.com/

APPENDIX III: STATE REGULATIONS

State	Cannabis Authority Website
Michigan	https://www.michigan.gov/cra
Minnesota	https://www.health.state.mn.us/people/cannabis
Mississippi	https://msdh.ms.gov/page/30,0,425.html
Missouri	https://health.mo.gov/safety/cannabis/index.php
Montana	https://mtrevenue.gov/cannabis/
Nevada	https://ccb.nv.gov/
New Hampshire	https://www.dhhs.nh.gov/programs-services/population-health/therapeutic-cannabis
New Jersey	https://www.nj.gov/cannabis/
New Mexico	https://www.rld.nm.gov/cannabis/
New York	https://cannabis.ny.gov/
North Dakota	https://www.hhs.nd.gov/mm
Ohio	https://medicalmarijuana.ohio.gov/
Oklahoma	https://oklahoma.gov/omma.html
Oregon	https://www.oregon.gov/olcc/marijuana/pages/default.aspx
Pennsylvania	Pennsylvania Medical Marijuana Program
Rhode Island	Office Of Cannabis Regulation | Dept. of Business Regulation
South Dakota	South Dakota Medical Cannabis Program
Virginia	http://cca.virginia.gov/
Vermont	https://ccb.vermont.gov/
Washington	https://lcb.wa.gov/
West Virginia	Office of Medical Cannabis

AMERICANS FOR SAFE ACCESS

118th Congress

COMPREHENSIVE MEDICAL CANNABIS & CANNABINOID LEGISLATION

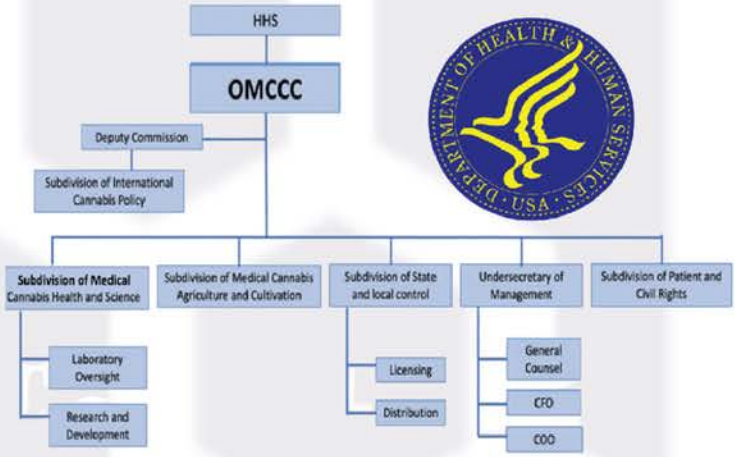
ANSWERING THE CALL OF STATE GOVERNMENTS, REGULATORS, PATIENTS, & MEDICAL PROFESSIONALS

Comprehensive medical cannabis and cannabinoid legislation is required to address the gap in state and federal cannabis policies, public health concerns, and to give federal agencies robust guidance they are seeking from Congress. **The Federal Guidance on Medical Cannabis & Cannabinoid Act Of 2023,** drafted by Americans for Safe Access with input from patient organizations, regulators, researchers, and medical professionals, has two primary functions: changing the schedule of cannabis to a newly created schedule (Schedule VI), and creating **the Office of Medical Cannabis and Cannabinoid Control (OMCCC)** housed under the U.S. Department of Health and Human Services (HHS).

A NEW AGENCY: OMCCC

The mission of the OMCCC is to facilitate access to medical cannabis for therapeutic use and research, regulate the production of medical cannabis and cannabinoid products, facilitate private-public partnerships for product development and research, and oversee the new Schedule VI.

The OMCCC will require initial federal funding however most operational funds will come from the reorganization of current cannabis oversight funding, licensing and permit fees, and private-public research partnerships.



A NEW SCHEDULE: Schedule VI

There is a national consensus that cannabis does not belong in Schedule I of the Controlled Substances Act ("CSA"). A status shared with heroin and a classification claiming it is considered more dangerous than cocaine, methamphetamine, OxyContin, and fentanyl (all Schedule II substances). The overwhelming majority of substances listed in the Controlled Substances Act are synthetic compounds, not natural products. Cannabis (and perhaps a few other natural substances) does not organically fit into the schedules described by the CSA.

Since 1996, states have been authorizing programs for cannabis that operate completely outside the prevue of the CSA. By amending 21 USC 812(b)(5) of the CSA to create a new scheduling category for cannabis, Schedule VI, Congress will maintain moderate control over medical cannabis and cannabinoids for human consumption, give clear guidance to federal and state agencies, while allowing the greatest number of patients to access cannabis as a medicine.

Americans for Safe Access
Advancing Legal Medical Cannabis Therapeutics

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THE FEDERAL GUIDANCE ON MEDICAL CANNABIS & CANNABINOID ACT IS NECESSARY

Clarify Federal Stance on Medical Cannabis & Cannabinoid Policy

- The Medical Cannabis amendment to the Commerce-Justice-Science (CJS) Appropriations bill, first passed in 2014, was meant to be a triage measure to stop raids and prosecutions while Congress dealt with federal medical cannabis policies.
- The Hemp Authorization of the 2018 Farm Bill removed cannabis with <.3% THC from the CSA and tasked the Food and Drug Administration (FDA) with regulating these products. Five years later, in January 2023, the FDA told Congress they cannot do it.
- There is confusion for federal agencies in dealing with cannabis, forcing many to create "workaround" policies for cannabis without the benefit of medical cannabis policy experts to guide them, and most agencies have found themselves in court trying to navigate the state-federal conflict.

States have Fulfilled their Role as "Laboratories of Democracy"

- Forty-one states, the District of Columbia, four of five U.S. territories have medical cannabis distribution programs, and seven states have cannabidiol laws.
- State policymakers and regulators have not only been tasked with creating the infrastructure and regulations for a supply chain that remains illegal at the federal level, but now, as seen in 99 pieces of legislation introduced in 2022 alone, they must address a new health concern of seemingly federally legal unregulated cannabinoid market created by the 2018 Farm Bill.
- The state-by-state compassionate use model leaves out those patients living in states reluctant to pass medical cannabis laws, federal employees and contractors, and veterans utilizing VA medical services. In states with medical cannabis laws, this model does not address many medical or logistical needs for patients, only serving a privileged class of Americans.

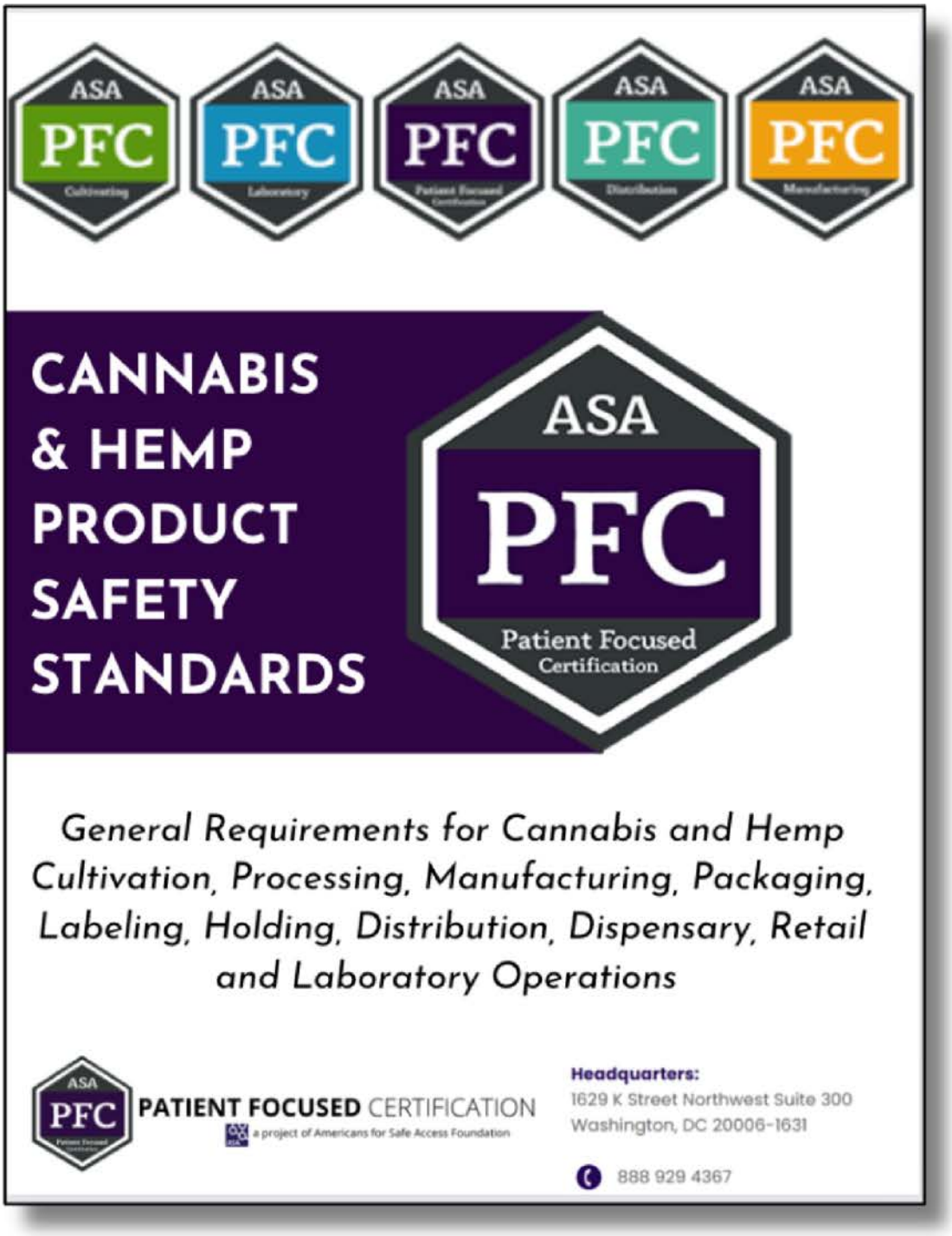
Science has Changed Understanding & Attitudes on Medical Cannabis

- 93% of Americans are in favor of medical cannabis policies.
- In 2020, the United Nations reclassified cannabis recognizing its medical benefits and over 60 countries have legalized the medical use of cannabis at the national level.
- 6 million Americans are using medical cannabis as a stand-alone or as an adjunct treatment to relieve symptoms or side effects experienced from other treatment methods. In many cases, patients, and their medical professionals report that cannabis and cannabinoids work where all traditional options have failed.
- In response to the U.S.'s pain and opioid epidemics, over 1/3 of Americans are turning to cannabis and cannabinoids to treat chronic pain and curb opioid use resulting in fewer opioid deaths in states where medical cannabis is available.

Download Full Text:
safeaccessnow.org/model_federal_legislation

ASA

For more information, please contact Americans for Safe Access info@safeaccessnow.org



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