Reducing Cannabis Testing and Label Failures

Effective risk management activities for cannabis companies

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To date, most of the claims and litigation around cannabis products have been predicated largely on allegations of contamination, mislabeling and testing failures that have resulted in product recalls, consumer class actions and alleged state regulatory violations or violations of consumer protection statutes. Testing failures place additional financial burdens on businesses because products that do not pass state testing requirements either are not allowed to be sold to the public or the product's value is reduced because of the cost of remediation. We expect that industry risk management advancements, along with the adoption of uniform standards for cultivation, manufacturing and testing, will help to drive down future liability for contamination, label inaccuracies, testing failures and similar claims. To be fully effective, these risk management activities should be formal, complete and – most importantly – embraced by cannabis companies at all levels of management.

Product Contamination

Contamination issues primarily involve pesticides (as well as herbicides and fungicides), solvents, heavy metals and microbiological contaminants. The cannabis industry has been hampered by the fact that the Environmental Protection Agency (EPA) does not regulate cannabis due to its Schedule 1 status, and therefore has provided the industry with no helpful scientific recommendations for pesticides and other agricultural chemicals. There has been little research on the risks of heating and inhaling pesticides used on agricultural products. States have therefore been left to make their own recommendations on chemicals that should be used or avoided. California and Colorado, in particular, have played a leading role in the development of state-issued cannabis pesticide recommendations. In lieu of federal participation, the active engagement of additional states and the adoption of formal risk management practices must play a more prominent role in providing guidance to the cannabis industry.

Even products that are characterized as "organic" or "minimum risk" may trigger lab failures, including for pesticides, solvents and heavy metals. This inadvertent contamination may be due to pesticide or heavy metal residue in the growing medium or nutrients used by the cultivator introduced through cross-contamination or pesticide drift. Residual solvents and cleaners used in other areas of a facility also may

trigger testing failures. Trace amounts of industrial or household chemicals can linger in cultivation areas for months after use.

Microbiological contaminants represent a primary area of uncertainty that impacts cannabis product liability. Many states' cannabis contaminant testing requirements are derived from food testing rules that specifically look for common food contaminants such as E. coli and salmonella. Although those contaminants are a significant threat in the production of marijuana edibles, the risk of common foodborne pathogens is lower in the cannabis plant and in cannabis extracts. Lesser known microbiological contaminants also may pose a danger to consumers. Various species of fungus can cause illness from mycotoxins, which can result in severe injury or even death when consumed. Lack of research has hampered the industry and its regulators from identifying and categorizing dangerous species of mold, mildew and other fungi. As we learn more about what mycotoxins may be found in and around the product and their specific health hazards, uniform testing standards should be improved and adopted to protect public health.

The Cannabis Testing Laboratory Trust Gap

The importance of uniform testing standards has been made more apparent by recent reports of negligence and even fraud committed by cannabis testing laboratories in multiple states. Although labs in most states essentially work on the "honor system," there is a significant trust gap due to the questionable business practices of a subset of licensed laboratories. In fact, lab failures have been an open secret within the cannabis industry for some time.

Lab Shopping

Cannabis testing laboratories are private for-profit businesses that rely on cultivators and distributors using their services. Reports of "lab shopping" and undisclosed *quid pro quo* deals between cannabis businesses and testing laboratories have become more frequent. It was reported in January 2021, for example, that Nevada laboratory Cannex was suspended for allegedly inflating THC potency results for favored clients, and repeatedly retesting samples for contamination until a passing result is obtained. Other reports have accused marijuana businesses and labs of adulterating product with spray-on cannabis oil that gives the impression of a higher THC content, a practice known as "kiefing." Some laboratories have lost their licenses based on violations of this nature.

Cherry-Picking

Some states allow the cultivator or distributor to self-select the sample to be tested, which may lead to biased "cherry-picking" and manipulated lab results. Some samples, for example, may be separated and carefully dried independently from the bulk harvested material to reduce the potential for findings of microbial contamination or moisture. Cherry-picking of samples also may lead to deficiencies in the testing for adequate homogeneity of cannabis-infused products. Batch-to-batch variability may be caused by factors such as changing growing conditions, the manufacturing environment or even use of different packaging.

Costs

A 2020 study from the University of California, Davis finds that safety tests cost growers about 10 percent of the average wholesale price of legal cannabis, with the biggest share of this expense due to test failures. California's lab testing requirements are the most stringent among state regulations, mandating testing for more than 100 contaminants, including 66 pesticides with tolerance levels as low as any agricultural product. The cost of testing in California averages around $500 per product tested.

Varying Methods and Equipment

Not only do states have varying standards for regulated testing laboratories, but the testing methods and validation procedures used by labs within the same state may vary widely. Although there can be a wide divergence in the quality of the equipment used by laboratories, instrumentation typically includes gas chromatography (GC) and high-performance liquid chromatography (HPLC) systems coupled with various modes of detection such as mass spectrometry and diode-array detection. HPLC often is used to measure cannabinoid concentration, and if done correctly, allows chemists to separate and measure the concentration of THC, CBD, terpenes, flavonoids and other cannabinoids. Labs also may isolate pesticides using this method and then assess their concentrations using mass spectrometry.

Details of each laboratory's procedures and validation methods are often proprietary. This results in an environment where it is difficult to validate the accuracy of cannabis test reports – a particular problem for multistate operators that expect consistency with their branded products across multiple states. Brand loyalty, of course, depends on product consistency and safety. State regulators are evaluating broad testing standards through organizations such as the Cannabis Regulators Association (CANNRA) and with the assistance of outside third-party standards organizations such as ASTM International, giving them a better understanding of the problems.

The "Limit-of-Detection" Problem

Some states inadvertently created perverse incentives by allowing a cannabis product to pass or fail through "limit-of-detection" testing. This standard essentially provides that the sample for certain pesticides or other contaminants will pass if the chemical is not detected within the limit of detection of the equipment and methodology used – but without setting a specific acceptable level of detection. This "detect/non-detect" standard penalizes laboratories with cutting-edge equipment and methods, while rewarding less proficient laboratories. A laboratory with modern equipment, experienced technicians and effective methodologies will detect pesticides or other contaminants at lower levels than a laboratory with older equipment, less experienced employees or ineffective methodologies.

From the cannabis operator's perspective, however, when faced with the choice between a more likely pass-rate for their product – even with a higher potential for recall – many operators will make the "easy" choice to get the product on the shelf. This dynamic should be reversed through the adoption of uniform standards that move away from limit-of-detection testing. In the meantime, states should examine and identify reasonable action levels for residual pesticides and solvents.

Label Inaccuracies Remain a Problem

In the meantime, various studies and surveys have verified label inaccuracies across a spectrum of cannabis products, particularly pertaining to "margin of error" cannabinoid potency testing and reporting of contaminants. Some cannabis products are certainly easier to analyze than others. More complex products such as cannabis edibles are more likely to be inaccurately labeled. For example, California's Bureau of Cannabis Control determined that nearly 20 percent of all products tested failed laboratory analysis for potency and purity, with the most common failure being inaccurate claims on the package label. Over 30 percent of edibles and other manufactured products failed.

Identifying the Solutions and the Barriers

Advancements with the adoption of uniform standards for cultivation, manufacturing and testing should help to drive down future liability for contamination and label claims, so long as the standards are followed by cannabis operators. Several key practices should be embraced by the cannabis testing industry, including full accreditation, objective demonstration of proficiency, better investment in state-of-the-art equipment and the adoption – and enforcement – of ethical business practices. Past experience in other market sectors such as health care, pharmaceutical and automotive tell us that compliance is not widely embraced unless certain disciplinary consequences are attached. Organizations such as the

Cannabis Compliance Commission of Nevada have been formed to police compliance, and penalties are being imposed for nonconformance to specific standards.

Accreditation

Given the concerns addressed above, it is a hopeful sign of progress that of the 26 states that currently mandate cannabis testing, 18 require some form of accreditation. This usually means accreditation through the International Organization for Standardization (ISO). The standard for testing laboratories is ISO 17025 ("General requirements for the competence of testing and calibration laboratories"), which sets minimum equipment, process and quality assurance requirements, as well as proficiency testing to ensure that testing methods are accurate. Some states either do not require ISO accreditation or allow laboratories to "phase in" for accreditation over time. In addition, of those cannabis testing laboratories that have some form of accreditation, a majority are accredited for only a few of the tests they perform. The industry should strive to require full accreditation on all compliance testing methodologies.

Proficiency Testing

No state has yet developed and implemented a cannabis proficiency testing program. Such a program could incorporate random sampling and testing of retail products off store shelves, with results compared to the testing laboratory's Certificate of Analysis for that product. Alternatively, proficiency testing may be coordinated by an independent third party that sends an unidentified sample to testing laboratories to verify whether the laboratory has the expertise to accurately analyze the ingredients. This system has been used for companies that test water, biofuels and certain agricultural products.

Striking the Right Balance

It may be difficult to achieve widespread consensus on what should be included in uniform testing standards due to disparate stakeholder interests. Stringent standards are more expensive to adopt. That may raise the barrier to entry for less-established companies and potentially stifle industry growth. Less rigorous standards, however, can result in unscrupulous laboratories undercutting responsible competitors through less-expensive and unreliable methods that could harm public safety and perpetuate the trust gap that already exists. Striking the right balance means adopting standards that allow some degree of flexibility for a still-emerging industry while keeping customers safe.

In the meantime, there are certain easy steps that have immediate impact on the safety of cannabis products. Broad adoption of Current Good Manufacturing Practice (cGMP) standards, for example,

should prevent most instances of microbiological and particulate contamination in cannabis-infused products.

Federal Illegality Doesn't Help

The challenge is further complicated by the ongoing federal illegality of cannabis and the resulting fragmented state commercial markets, which make a uniform national standard all but impossible without reform at the federal level. The current population of licensed laboratories is almost exclusively composed of small state-specific startups that do not maintain federal DEA licenses like their non-cannabis competitors. In addition to making a uniform standard more achievable, reform at the federal level should help pave the way for important new players, such as large food safety laboratories and experienced manufacturing professionals, to enter the space. This may facilitate improved quality assurance with a corresponding reduction in product recalls, label suits and consumer class actions.

Like cannabis banking reform, redressing the federal illegality of cannabis products should be championed as a public safety measure due to the positive impact it will have on the future safety and integrity of the entire cannabis product supply chain – with sound risk management practices and accredited bodies such as cannabis testing laboratories at its center.