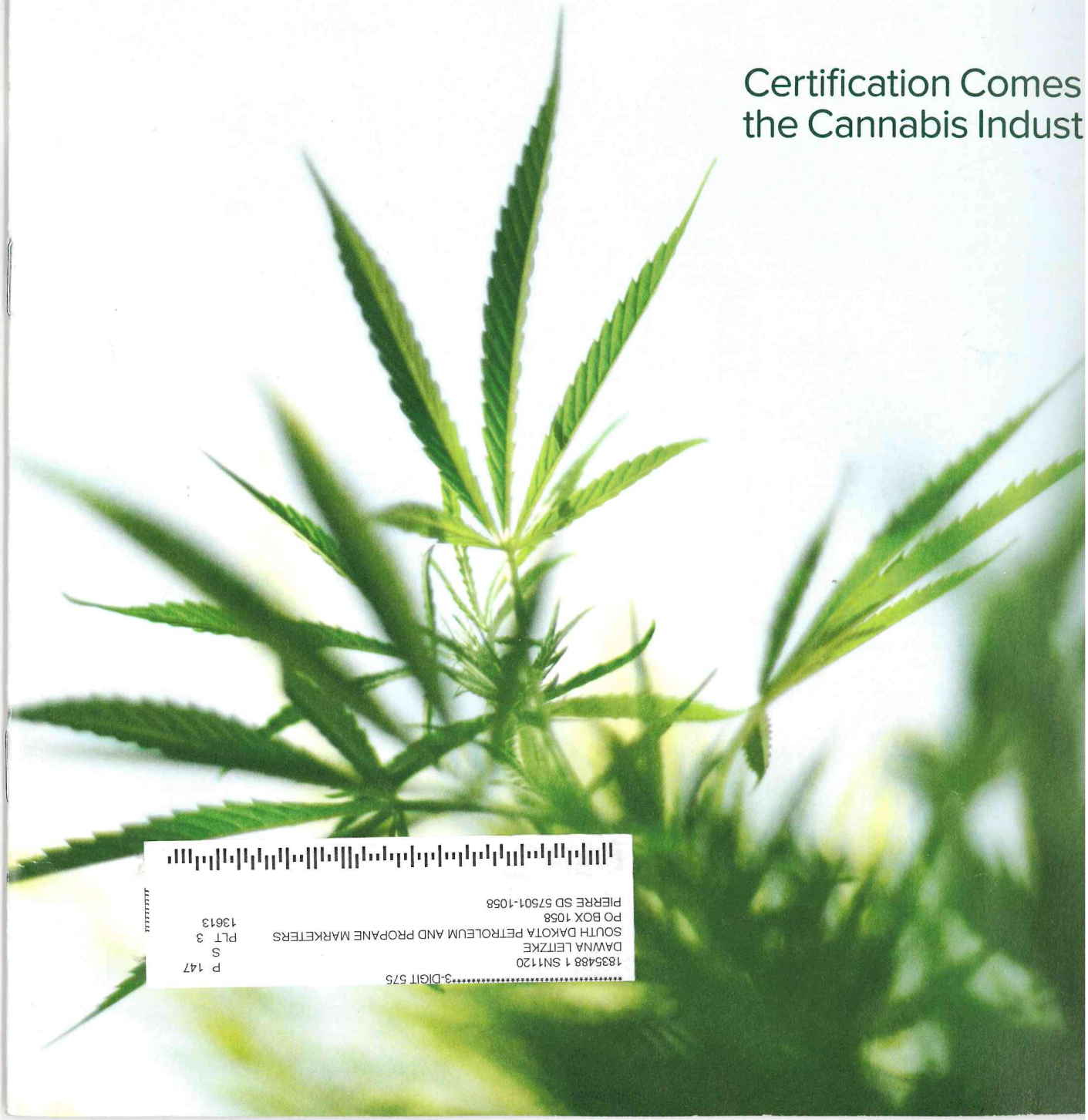
NOVEMBER/
DECEMBER 2020
WWW.ASTM.ORG/SN

STANDARDIZATIONNEW

Certification Comes
the Cannabis Indust



Editor's Note
The Cannabis Industry Grows

It doesn't seem long ago that a formal, organized cannabis industry did not exist. Within the lifetimes of many readers, the use of hemp as a construction material or cannabis as a medical treatment were not mainstream. However, a shift in public sentiment in recent years has led to cannabis becoming big business.

According to a recent study from Grand View Research, the global cannabis market is predicted to grow to nearly $74 billion USD by 2027, up from $15 billion USD in 2019. That represents a growth rate of nearly 500% in the next decade, remarkable by any measure. And yet, while great strides have been made in recent years, the cannabis market is still in urgent need of standardization to keep up with its rapid growth – and to facilitate future growth.

One major issue being addressed in the cannabis sector today involves certification. Just as vegetables are certified organic or children's sports equipment is certified for safety, one of the biggest pushes in the standards community at the moment involves the certification of cannabis growers. And ASTM International's committee on cannabis (D37), working with industry players such as The Good Manufacturing Practices (GMP) Collective and the Safety Equipment Institute (SEI, an ASTM affiliate), has been working toward developing a certification program for the cannabis industry. These efforts, including a blueprint for certification, are described in detail on page 20.

Another issue that will have a major impact on the future growth of the cannabis industry is that of representative sampling of cannabis and hemp crops. As in other areas of agriculture, the need to measure contaminants as well as potency is critical, and obtaining representative samples can at times be a destructive — and costly — process. The effort to streamline and make the sampling process uniform is underway in the committee on cannabis, and their work on this issue is described on page 24 . Best practices, as well as a guide to sampling, are currently being developed and will soon make their way to market.

The cannabis industry has certainly come a long way in recent years. An industry that essentially did not exist just a few decades ago is now a multi-billion dollar industry. And like many other global industries, it is in need of standards and related programs. This will be the key to the safe and efficient growth of this emerging market, and ASTM's cannabis committee is leading the way.

David Walsh
Editor in Chief

@ dwalsh@astm.org
@ASTMeditor
www.linkedin.com/in/dwalsh11

Send letters to the editor to dwalsh@astm.org. Letters should not exceed 200 words and may be edited for clarity or space limitations. Letters are fact checked, and we confer with letter writers about editing to the extent that deadlines allow.

ASTM Standardization News, Volume 47, Number 6 (ISSN 1094-4656) is the official bimonthly magazine of ASTM International, 100 Barr Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428-2959. Subscriptions: 1 year, $20. Single copies, $5.00. Periodicals postage paid at W. Conshohocken, PA, and at additional mailing offices. Postmaster: Send address change to ASTM International, 100 Barr Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428-2959.

The Need for Cannabis Standards

An Interview with **Ralph Paroli, Ph.D.,** National Research Council of Canada, and Chair of ASTM International's Cannabis Committee

Q You have long been involved with ASTM and work on committees such as roofing and waterproofing (D08) and rubber and rubber-like materials (D11), which are seemingly unrelated to cannabis. How did you then become chair of the cannabis committee?

A In many ways, that is the first reaction many people have. Believe it or not, there are many members in this field who have a background in construction. If you think about it, many of the materials and systems required for greenhouses are from standard building materials and systems.

My involvement had to do with timing more than anything else. I was chair of the board in 2016, and it also was around that time that the Government of Canada announced plans to legalize cannabis. I was looking at what role, if any, NRC [National Research Council of Canada] Metrology would play and thought of normative standards as well as reference materials because of the problems that the industry was mentioning (e.g., different labs gave different results).

I then discussed with Dan Smith [ASTM's vice president, technical committee operations] the need for standards in this area, and he said that I was the second person to raise this issue. From there, at an NCSLI meeting, I gave a conference keynote on the need for standards and how ASTM could work in this area. The second keynote was Jeremy Applen, who is now the D37 vice chair. We just kept being part of discussions with ASTM staff. The rest, as they say, is history.

Q Why are standards needed for cannabis?

A A big issue is related to safe consumption. Many users have health issues and are looking at using cannabis for relief from these issues. Others are using it for recreational purposes.

Whichever the purpose, people need to know that they are consuming something that is fit-for-consumption. People need to know how much they are consuming, what the components are, whether the delivery devices are safe, if the material was stored properly, and so on.

Standards are also needed to ensure that the producers of goods know what they are selling both in terms of the quantity of THC and the quality of the product (e.g., absence of pesticides, etc.). It will help with sales and exports and imports.

Q How are cannabis standards relevant in regulation, certification, and industry?

A That is a big part of several subcommittees. All areas are important, but for there to be a safe and reliable supply of cannabis, all parties involved need to have the proper standards available to them.

For certification to be effective and credible, one needs to know how to evaluate the cannabis product and what to evaluate for. Industry wants to be able to demonstrate that they are reliable and have a safe product, so they want to demonstrate that they meet standards. This is how the industry as a whole will gain credibility.

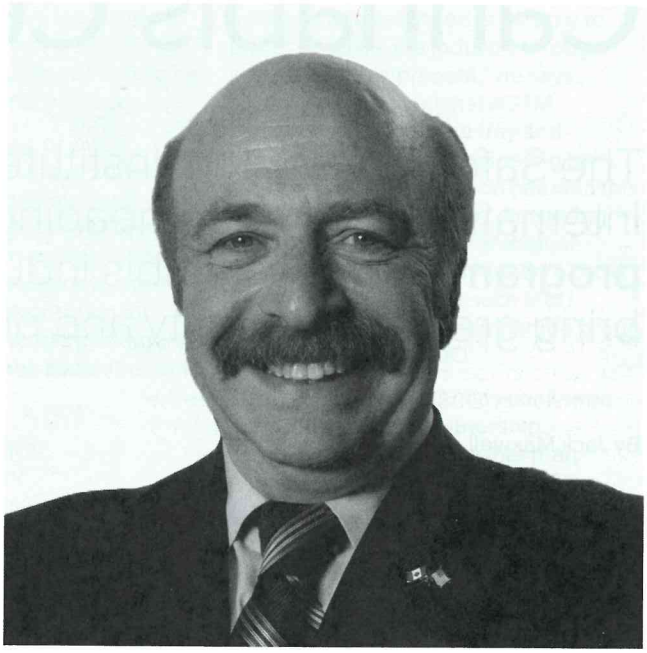
Q How would you characterize the cannabis committee?

A The members of D37 are very committed and engaged. To their credit, they saw that the road to being considered a legitimate sector was through standards. We are fortunate to have a committed group of leaders on the executive subcommittee who are dynamic and engage many volunteers to help develop standards. We are also fortunate to have someone like Bob Morgan as our staff manager. He has been a great resource for the committee, especially given that the majority of our members are new to ASTM.

The momentum is there. That is why we have developed 15 standards with many more in the works. We have over 900 members from around the world — 26 countries in total. The record for distance traveled goes to one of our members from New Zealand, who came to the United States specifically for our committee week. As is usually the case for committees, it is all about the members. They are identifying the pressing needs for standard development, and they are willing to take the pen and write the standards that the entire committee then weighs in on. Luckily, ASTM has many templates that help guide standards development.

Q What would you consider the most important issue facing the cannabis industry right now, and how would standards help solve it?

A Ultimately, credibility is the biggest issue. Consumers need to know what they are getting and that if they choose to consume, it will be free of pesticides, etc. They need to know how much they are consuming, and they need to know that should a problem occur, there will be a means of identifying the problem and that a recall will take place. They need to know that it was processed properly and they need to know that the method of delivery is reliable, does not contain heavy metals, and more. ■



Ralph M. Paroli, Ph.D., is director general (acting), for the Metrology Research Centre at the National Research Council of Canada in Ottawa, Ontario. Chair of the committee on cannabis (D37), Paroli is a former chair of the ASTM International board. He is also a past chair of the committee on roofing and waterproofing (D08), a section chair in the committee on rubber and rubber-like materials (D11) as well as a member of other ASTM committees.

Cannabis Certification

The Safety Equipment Institute and ASTM International are spearheading a **new certification program** for the cannabis industry that promises to bring greater uniformity and promote growth.

By Jack Maxwell

The history of cannabis, especially over the last 60 years, is intertwined with social and cultural changes that have transformed many aspects of life around the world. And although in some quarters, resistance to the more widespread acceptance of cannabis-related products continues, the numbers speak for themselves. According to one estimate from New Frontier Data, the industry could generate total sales of $23 billion in the United States alone by 2025 — and much more around the globe.

Clearly, cannabis is on its way to becoming the kind of big business many of its advocates have shunned over the years. Yet at the most basic level, marijuana and hemp are plants. Growing them successfully is fraught with the same kinds of challenges facing any farmer who plants a crop and hopes to see healthy green shoots emerging from the earth.

Of course, it's what's different about cannabis that presents a challenge to growers, as well as processors, packagers, retailers, and those charged with regulating the industry. For one thing, soybeans, corn, and other traditional crops do not have psychoactive properties. And until recently, cannabis had not been cultivated, processed, and packaged at the scale common to more traditional crops.

In the United States, it was just eight years ago that Colorado and Washington became the first states to legalize the recreational use of marijuana. They've since been joined by 10 other states and the District of Columbia. California was the first state to legalize medical marijuana in 1996, and since then, 27 more states have followed suit, structuring their programs in a variety of different ways.

The same trends can be seen around the world. Canada, Georgia, South Africa, and Uruguay have legalized recreational use, and more than 40 countries allow cannabis products to be prescribed for medicinal purposes.

The inconsistent mosaic of laws and regulations in the United States creates a degree of confusion and hampers larger cannabis producers who want to operate in multiple states. To address this problem, a new effort to create a certification program for cultivators, processors, and packagers is taking place within the committee on cannabis (D37).

A BIT OF AGRICULTURAL STANDARDS HISTORY

While many people think of manufacturing, construction, and advanced technology when they think of ASTM International standards, the organization also has a long history related to agriculture. Agriculture-related standards have been developed by various ASTM committees and cover key elements such as infrastructure, field and evaluation equipment, pesticides, and product safety.

The cannabis committee is building on this history. Although formed less than four years ago in February 2017, the committee has been very busy. Its 10 subcommittees have already published 15 standards, and some 70 additional work items are in the pipeline. Perhaps just as important, the involvement of an international standards development organization (SDO) and its consensus procedures have given valuable legitimacy and balance to the cannabis ecosystem.

The American Trade Association for Cannabis and Hemp (ATACH) is one of the leading advocacy groups for the industry. Michael Bronstein is president and co-founder. "We partnered with ASTM International almost immediately as the D37 committee was formed, and we saw a real need to be able to professionalize the industry through standards development," he says. "We were overjoyed that ASTM decided to step into the fray and meet the challenge, considering the credibility the organization has with this particular subject matter." According to Bronstein, the memorandum of understanding (MoU) between ATACH and ASTM was the first such MoU signed by a cannabis/hemp trade group and an accredited SDO.

The work done by D37 has confirmed the wisdom of this partnership. For evidence, look no further than the widely accepted standards for determining (D8196) and maintaining acceptable (D8197) water activity in cannabis flower, two of the committee's major accomplishments so far — and just two of a number of ASTM standards that underpin the new ASTM Cannabis Certification Program. As outlined below, these are the standards cannabis operators will have to meet in order to achieve certification.

THE ASTM CANNABIS CERTIFICATION PROGRAM

When a highly motivated group of stakeholders, working in the well-established consensus-building ASTM International framework, decides that their industry urgently needs a new test method or certification program, things can start moving quickly. The Cannabis Certification Program is an excellent example.

"Thanks to the incredible work of D37, the SEI team, and The GMP Collective, the certification program went from discussion to outline to full-on handbook in just a few months," says Charlie Rutherford, ASTM consultant and a D37 member. He is also the

founder of CPR Squared, a cannabis consulting firm. "We're in the pilot phase, where we're taking a handful of license holders through the program to work out some of the finer details, so that a brand wearing the ASTM-certified seal will be rightly seen as an industry leader in quality management."

Rutherford notes that operators in some states must obtain distinct licenses for each phase of the production process: cultivation, processing (the step during which cannabinoids, terpenes, and other active ingredients are extracted and concentrated for use in products like edibles and tinctures), and packaging. "These could be separate licenses held by the same company," he says. "We wanted to provide a pathway for any cannabis-touching business to get certified."

The Safety Equipment Institute (SEI), an ASTM affiliate, will administer the program in partnership with GMP Collective.

Tricia Hock is SEI's director of certification operations. "Cannabis cultivators, processors, and packagers will become SEI participants, and from there we will work with them to audit their facilities and ensure that they meet industry standards for quality and cleanliness, and are safe and secure," she explains. "We will also be testing product such as cannabis flower from cultivation facilities to ensure it meets the ASTM standard for water activity."

GMP Collective works with cannabis and hemp producers to implement strict good manufacturing practices (or GMP). The company was chosen as the audit manager for the program by the ASTM committee members and other stakeholders who developed it. In that role, GMP will conduct the actual audits and manage overall audit traffic.

David Vaillencourt, GMP's chief executive officer, was instrumental in helping to incorporate key aspects of both good manufacturing and good agricultural practices in the new certification program. He emphasizes the importance of a broad-based, national quality initiative in the currently fragmented cannabis marketplace.

"The major challenge for operators is that they're required to meet stringent and ever-evolving compliance requirements that differ from state to state," Vaillencourt says. "However, a quality system is effective and applies across all jurisdictions and operations. Thus it has significant value. Establishing specifications and requirements based on your stakeholders — for example, regulators, consumers, buyers — whether business-to-business or business-to-consumer; documenting these criteria; and showing evidence that you have systems in place to hold your company accountable for meeting these criteria, are what quality systems are all about."

AUDITING CANNABIS FACILITIES

When it comes to inspecting a cannabis operation, the same basic principles apply as those used during quality management system audits conducted under the auspices of groups like the International Organization for Standardization (ISO). The process will evaluate how an operator handles design changes, inspection of incoming materials and outgoing merchandise, and issues with complaints and noncompliant product.

Vaillencourt describes how that process is designed to work in the context of the Cannabis Certification Program. "We will assess a facility's best practices by reviewing their documents — policies, procedures, records — walking their facility, and looking for evidence of these documents being followed and appropriately and accurately completed, and potentially interviewing personnel on the floor. All aspects of the production operation plus quality and compliance will be examined."

According to Hock, the audit procedu will focus on four particular areas: quality management system (QMS) review, good manufacturing practice cleaning and disinfection processes, and security and surveillance system

The QMS review will include 19 specific elements (see sidebar), referencing ASTM standards coverin implementation of corrective action a preventive action (CAPA), including th guide for CAPA for cannabis industry procedures (D8229); applying a hazar analysis critical control points (HACCI system (D8250); processing of produ complaints (D8286); and standard practice for compliance audits (D830

Hock says that three other standards from the committee that address security — video surveillance (D8205 access control (D8217), and intrusion detection (D8218) — will be used to determine how well a cannabis facility is protected against theft and unauthorized individuals. In addition, the guide for cleaning and disinfectio of a cannabis cultivation center (D821 will be the benchmark for evaluating a facility's commitment to maintaining proper levels of cleanliness.

The audit process involves more than a one-time visit. As Rutherford points out, "The biggest weakness of an onsite inspection is that it's literally a snapshot in time. Many of these facilities are operating 365 days a yea We see one day. What happens on the

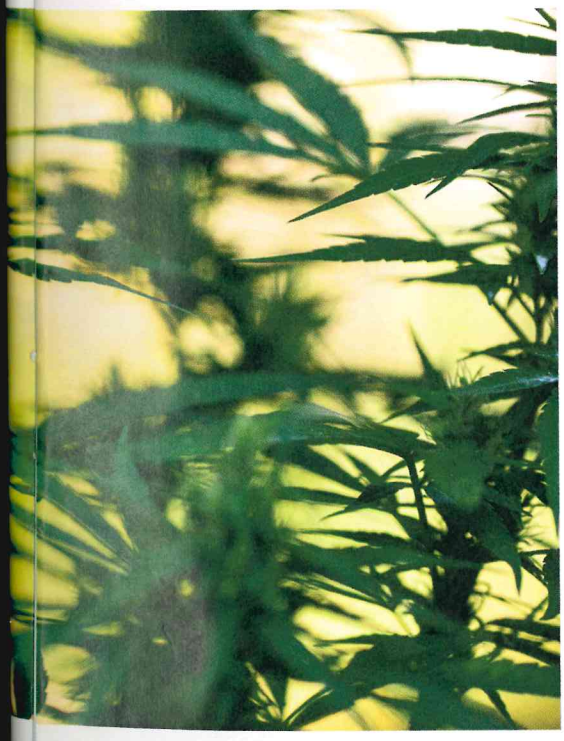
Cannabis Certification QMS Review Elements

The elements will include:

- Quality policy
- Organizational structure
- Design control and change
- Document control
- Purchasing process and records
- Infrastructure
- Product traceability
- Process control
- Preservation of product
- Inspection and testing
- Control of inspection, measuring, and testing equipment
- Control of nonconforming product
- Complaints and corrective and preventative action
- Control of quality records
- Internal quality audits
- Training
- Distribution
- Recall
- Use of the SEI certification mark

ASTM INTERNATIONAL

Certified



other 364?" One way the certification program administrators will gain a more complete picture of a facility's quality performance is to obtain product samples randomly throughout the year and send them to a third-party laboratory for testing.

Audits will inevitably uncover nonconformance issues. However, the purpose is not to assign blame or call out mistakes but rather to drive continuous improvement. The ultimate goal is to ensure that the people who own and manage cannabis facilities recognize the importance of meeting industry standards. "They need to have a demonstrated commitment to quality, with evidence that senior management, regardless of how big or small their organization is, takes quality and product safety seriously," Vaillencourt says.

The reward? "Upon successful completion of the quality audit and product testing, the cultivator will be able to use the ASTM Certification Mark on their product and marketing materials," Hock says. "The Certification Mark is an indication to regulators and consumers that this product is safe and was produced at a high-quality cultivating facility."

THE ROLLOUT

Cannabis, like any plant material, can be affected by a variety of contaminants. As the industry continues to grow and expand into additional states, the potential for problems to occur also increases, especially given the current absence of any kind of uniform standards. To list just a few examples:

- In 2018, 13% of final cannabis batches failed total yeast and mold tests in Colorado.
- The Oklahoma Medical Marijuana Authority issued its first recall of tainted cannabis products in May of 2020 when vape cartridges and mints tested for higher-than-allowed amounts of pesticide.
- In July 2020, a number of hemp products targeted to both pets and humans were voluntarily recalled after the Florida Department of Health notified the manufacturer of lead contamination.
- In August 2020, Michigan's Marijuana Regulatory Agency announced the recall of 3,200 marijuana cigarettes after finding worker contamination during the production process.

Agencies that are charged with ensuring the safety of cannabis products being distributed and consumed in their jurisdictions are very interested in the kind of widely accepted standards that will result from the work of the committee on cannabis.

"At the state level, attorneys general and other law enforcement officials, legislators, and regulators are continuing to look at what standards have been developed," says Bronstein. "The standards development process has been critical to assessing quality control in the industry and promoting public health and safety in ways that regulators are used to seeing."

As anyone who has participated on an ASTM committee knows, getting a new standard passed may not be easy. The rigor of the process provides an extra level of credibility. "When there's participation from regulators, there's participation from industry, there's participation from everybody who might have a stake in it, it's considered kind of the gold standard, and that provides real evidence as to what should be adopted and when it should be adopted," Bronstein notes.

He also cites ASTM's value as a forum for discussion. "The thing that our state-level partners have really valued in the ASTM relationship and with us is that there is a place where they can come and talk about some of the things they're seeing in their own markets. Then we can figure out a way not only to assist, but also to use those lessons in standards-making and apply them to the regulatory environment."

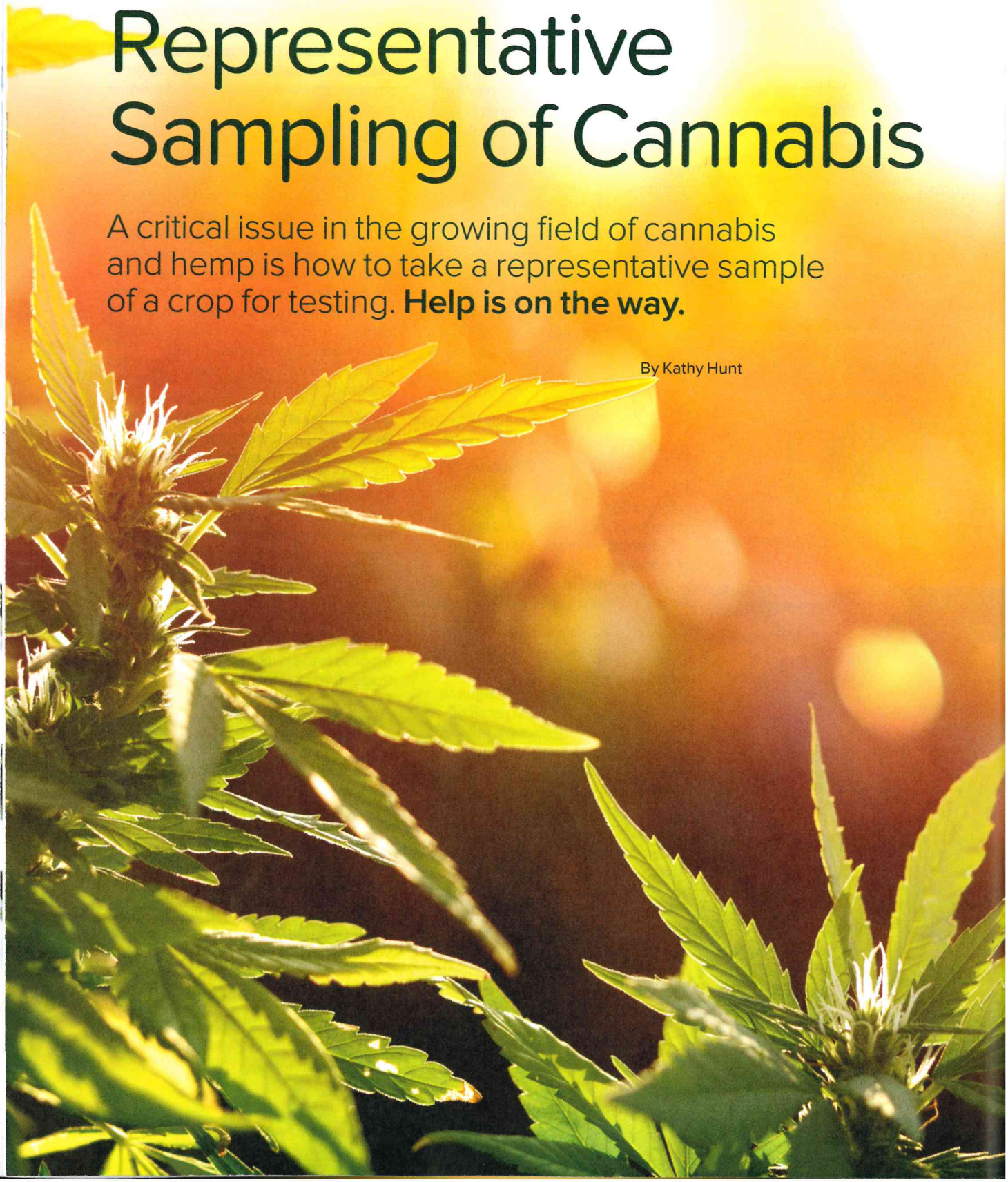
The next step in this collaborative process is the pilot program that Rutherford mentions. ASTM, ATACH, SEI, and the Policy Center for Public Health and Safety are working with several cannabis companies to implement the program and evaluate its performance. The results will be presented to members of the bipartisan Cannabis Policy Committee of the National Association of Attorneys General for review and consideration. Their feedback, as well as the experiences of the firms participating in the pilot, will be used to fine-tune the certification program in advance of a wider rollout. ■

Jack Maxwell is a freelance writer based in Westmont, New Jersey

Representative Sampling of Cannabis

A critical issue in the growing field of cannabis and hemp is how to take a representative sample of a crop for testing. **Help is on the way.**

By Kathy Hunt



Over the past 20 years, public opinion on cannabis has seen a slow but steady shift. Once considered a gateway to further drug use, cannabis is now lauded for its ability to help manage pain, regulate seizures, and aid with anxiety and sleep disorders. Prescribed by physicians and used by over two million U.S. patients in 2018, medical marijuana has entered the mainstream.

To date, 46 countries have legalized medical cannabis. Of these, more than 30 have also decriminalized its recreational use. Four countries, including Canada, as well as 11 U.S. states and Washington, D.C., have legalized both recreational and medical marijuana. More are expected to follow suit.

Hemp has seen a similar shift. Used in textiles since ancient times, this cannabis variety has gained widespread recognition for its durable cellulosic and woody fibers, wholesome oil, fast growth, and ability to control erosion. Today, over 30 countries, including the United States, produce industrial hemp.

Increased use means increased production, which in turn necessitates standards for sampling and testing cannabis batches to ensure product quality and consumer safety. To address this need, the subcommittee on laboratory (D37.03), part of the cannabis committee (D37), is developing 26 laboratory-related and testing standards, including the practice for the sampling of cannabis/hemp post-harvest batches for laboratory analysis (WK64336). The proposed standard describes how to gather representative samples of cannabis/hemp inflorescence — the flowering part of the plant, including stalks and stems — for post-harvest lab analysis.

THE COMPLEXITIES OF POST-HARVEST BATCH SAMPLING

Developing standards for cannabis is no easy task. Cannabis is a complex plant genus with two primary varieties: *cannabis sativa* and *cannabis indica*. The plants contain a wealth of chemical compounds, including the familiar cannabinoids tetrahydrocannabinol (THC) and cannabidiol (CBD). THC and CBD, the most predominant and commonly occurring cannabinoids, are extremely similar in molecular makeup. Yet, THC produces a high or sense of euphoria that CBD does not. Because CBD has some of THC's therapeutic benefits but none of its particular psychoactive effects, it is used to treat an array of health disorders.

Within a given plant, the amount of cannabinoids present can be influenced by an assortment of factors, including the gender of the plant, individual strain, temperature, water, sunlight, condition of the soil, and the plant's exposure to chemicals. The cannabinoids' location in a plant also may vary. THC levels may be higher in the buds but lower in the stalks of a specific plant. Yet, in a neighboring plant of the same cultivar, the reverse may be true.

As a result of these irregularities, accumulating representative samples can be difficult. David Vaillencourt is recording secretary for the laboratory subcommittee, CEO of The GMP Collective, and a member of the International Society for Pharmaceutical Engineering. He points out that, similar to tomatoes, which grow in slightly different shapes and sizes, cannabis varies not only from harvest to harvest but also from plant to plant. "We have to remember that this is a natural product. Therefore, you have to create a batch size that allows you to take a representative sample by helping to homogenize or eliminate some of that variability," he says.

Batch sample size can also be problematic, especially for growers. In sampling, the grower must lose a portion of his or her financially valuable crop. Whatever goes into a batch for sampling cannot be sold. The larger the sample, the more product and money the farmer loses. The subcommittee is still considering the actual size of post-harvest batches, and the published standard will include a suggested appropriate amount.

Another complexity is that the basic definition of a cannabis/hemp harvest batch differs across the United States. According to Connecticut's Department of Consumer Protection, a batch is "a specific harvest of marijuana or marijuana products that is identifiable by a batch number." Meanwhile, California law describes it as a "specifically identified quantity of dried flower or trim, leaves, and other cannabis plant matter that is uniform in strain, harvested at the same time, and, if applicable, cultivated using the same pesticides and other agricultural chemicals, and harvested at the same time."

Cary Black, CEO and principal consultant of CK Black Group and chair of D37's subcommittee on accreditation, certification, and training (D37.06), is working on this standard, among several others. He notes these discrepancies. "Right now it's the 'Wild West' out there. You have different states with different regulations and different protocols. Many times the analyses that labs conduct are very different. You could send one batch of cannabis to three different labs and get

three different results. Standardized sampling has been a clear need right from the beginning. It minimizes the probability of error propagation. It's very important for accuracy and understanding what you have in your product and what people are putting into their bodies," Black says.

BEST PRACTICES FOR CANNABIS/ HEMP SAMPLING

To establish a best practice for sampling cannabis, the subcommittee first outlined a series of steps that should be followed. These are covered in WK64336.

First, the person doing the sampling must have access to the full post-harvest batch. That individual then randomly samples the batch of harvested cannabis, visually assessing the samples to help ensure that they represent the entire batch. If the cannabis buds appear consistent in color and state, sampling can continue. If some look brownish and deteriorated while others are green and fresh, the sampling should stop at this point. From a visual perspective, representativeness has been lost.

"There is always a continuous verification of the representative nature of the batch from a visual perspective," says Black. "Representativeness needs to be continued as the samples get to the lab. These need to be homogenized properly and have the same techniques used so that you're not introducing bias. The end result is having a sample that's representative of the characteristics of that batch. We're really trying to minimize the introduction of errors, at least on the sampling side of it."

WHAT TESTING CANNABIS REVEALS

When testing post-harvest batches, laboratories look at cannabinoid potency, particularly that of THC. In the United States, where federal law categorizes THC as a Schedule 1 controlled substance, the legal THC potency level is less than 0.3%. Any crops over the legal THC limit are considered "hot crops." They cannot be used for human consumption and must be destroyed. Not doing so would result in fines to the grower and possible prosecution.

Other countries have much less stringent regulations regarding cannabinoid potency. In the Netherlands, where the government oversees the distribution of medical cannabis through the Office of Medicinal Cannabis, THC amounts are based on a patient's need. Prescribed in the Netherlands for a range of conditions including cancer and tics resulting from Tourette's Syndrome, cannabis can possess a THC level ranging from less than 1% up to 22%.

Along with cannabinoid strength, lab testing of post-harvest batches determines microbiological activity, including the presence of mold, fungi, and bacteria in the cannabis. Testing also indicates the concentration of trace metals, pesticides, and terpenes. As part of the plants' essential oils, terpenes give cannabis its complex fragrance and flavor.

Black says that various factors can impact the plant and its usefulness. "There are many potential toxic moieties that could be associated with pesticides. The plant itself has a very high absorptive proclivity to pull in heavy metals from the soil that it grows in. It is prone to mold growth and aflatoxins. All of these represent significant hazards to consumers. It's really important for it to be screened adequately and to be sure that batch samples are representative to ensure consumer safety," he says.

Ultimately, lab testing and its associated results can impact cannabis quality control and regulatory requirements. This work can provide transparency and truth in labeling, two things that are lacking in the current cannabis market, says Darwin Millard, co-chair of the industrial hemp subcommittee (D37.07) and founder and owner of TSOC LLC.

According to Millard, another hurdle for the cannabis industry is that it does not always assist consumers trying to make sound, informed decisions. Currently, the industry tests for THC but not always for CBD content. As a result, CBD levels can fluctuate widely, with producers inaccurately stating how much CBD is in their product. This can lead consumers to believe that the CBD content is higher or lower than it actually is.

A 2019 study conducted by Ellipse Analytics (Denver, Colorado) found that over half of the 240 products tested by its lab did not possess the amount of CBD indicated by the producer. In many instances, little to no CBD was present. In some cases, though, the product had up to six times the amount of CBD listed on its label.

> It's one thing to require certain information on a label, but if the data isn't representative of the product inside the package, then what good is it?
>
> — Darwin Millard, TSOC LLC

"It's one thing to require certain information on a label, but if the data isn't representative of the product inside the package, then what good is it? This sampling standard is only one part of a larger set of standards that can be used to support each other in ensuring product quality and environmental and public health and safety," Millard says.

"As federal legalization and increased cannabis usage become more predominant, the need for transparency becomes critical," Black says. "As consultants/stakeholders in the industry and the creators of standards, we are working with people at the individual state levels and at the federal level to bring all these disparities together in a unified whole. This unification will be driven by standardization and support transparency."

AN INTEGRAL PART IN A LARGER SERIES OF STANDARDS

While valuable on its own, the proposed sampling standard (WK64336) plays an equally important part in a series of proposed standards from the laboratory subcommittee. Among this series is the proposed practice for sampling of field and bulk harvest lots of cannabis for laboratory analysis (WK73730). This proposed standard details strategies for in-the-field, pre-harvest sampling. It includes procedures designed to minimize the variability intrinsic to cultivated cannabis.

Another related proposed standard is the guide for representative sampling of cannabis extracts and derivatives for analytical testing (WK64646). According to Black, the work item covers typical, manufacturing-based, quality-control sampling standards as defined by traditional military sampling plan standards and codified in American National Standards Institute (ANSI)/American Society for Quality (ASQ) documents (ANSI/ASQ Z1.4 and ANSI/ASQ_Z1.9). The subcommittee references these ANSI/ASQ standards in WK64646. Similar to the proposed standard on sampling field and bulk harvest lots, this proposed standard aims to minimize the lack of homogeneity in cannabis.

"We are hoping to promote a way of sampling that optimizes the representativeness of the sampling exercise, taking into account those areas that provide the greatest variability in testing results, such as potency and phytochemistry," Black says.

He adds that there are sampling standards in the works for hemp seeds, which fall under the jurisdiction of the industrial hemp subcommittee (D37.07). The group developing WK64336 is working with this subcommittee and others to ensure harmonization across ASTM cannabis-sampling standards.

"When it comes to standardization of the cannabis industry, there is a lot of analysis and a lot of science needed to verify product safety," Black says. "As the industry progresses, follow specific safety guidelines will be required, whether they're from the FDA, EU, or the like. The more we can do to standardize those elements, the more seamless it will be to go into a regulated industry."

"What we find nearly every day, as we go through the development process of standards, is the need for a supporting standard or a supporting research and development effort," says Millard. "This is just the tip of the iceberg, so to speak. The work has only just begun. We need help, and we need subject matter experts who have the passion and drive to shape this industry to join ASTM International and D37."

The committee and subcommittees officially meet twice a year. However, ad hoc meetings of members engaged in the standards development process are held all year long. If you are interested in becoming part of the conversation about and assisting with the development of cannabis standards, please contact:

Cary Black, CK Black Group Inc.
cary@ckblackgroup.com
tel +1.989.737.4486

Darwin Millard, TSOC LLC
darwin@thespockofcannabis.com
tel +1.720.839.0559)

Robert Morgan, ASTM
rmorgan@astm.org
tel +1.610.832.9732

■

Kathy Hunt is an East Coast-based journalist and author.