



Cannabis Analytical
Science Program

AOAC PROGRAM TO DELIVER ANALYTICAL SOLUTIONS FOR ANALYSIS OF CANNABIS AND HEMP

As a global leader in food and agriculture safety standards and analytical methods, AOAC INTERNATIONAL is answering the call of regulators and private sector laboratories to convene experts and approve consensus methods for the analysis of cannabis and hemp in food, feed, plant materials, or other substances of interest to determine the best available science to promote public health. AOAC launched a new program, Cannabis Analytical Science Program (CASP), in conjunction with the AOAC Midyear Meeting in March 2019, to provide a forum where the science of hemp and cannabis analysis can be examined and for the development and maintenance of cannabis standards and methods. The CASP analytical community comprises government, academic, and contract laboratories; technology providers; private sector organizations; and allied associations. >>

"AOAC began work on cannabis 2 years ago on an ad hoc basis [see sidebar on AOAC cannabis-related activities]," said AOAC Executive Director **David B. Schmidt**. "The launch of CASP represents a major commitment by AOAC and the laboratory community to use analytical science to promote public health."

"Currently, no globally recognized standards and methods exist for validating the safety, potency, and label claims of cannabis products available to consumers," said **Seth Wong**, TEQ Analytical Laboratories. "This undermines public confidence and exposes the cannabis industry to risk."

"As one of the world's oldest and most trusted leaders in consensus scientific standards for food safety, AOAC is uniquely placed to play a key role," he added.

Worldwide, more than 50 countries permit regulated medical cannabis. In the United States, 47 states have legalized cannabis in one form or another addressing an adult-use market of 80 million people (*New Frontier Data*, State of the Cannabis Union, 2019). The U.S. cannabis industry's projected total market sales are estimated to exceed US \$24 billion by 2025 (*Forbes*, Marijuana Industry Projected to Create More Jobs than Manufacturing by 2020, 2017).

The federal farm bill allows cannabis plants with a low level of THC, but growers, dealers, and processors must register with the state government.

Although (medical) cannabis is becoming legalized in many states, many evolving regulatory, law enforcement, and other issues exist surrounding the growing industry. For example, while it's legal for properly registered people to possess industrial hemp—cannabis with a THC content of 0.3% or lower—it's still not legal to possess marijuana. Currently, there are no validated methods or rapid field tests that can readily differentiate legally possessed hemp from illegal marijuana. Field tests are available that are reliable enough to indicate a substance is cannabis, but these tests cannot discern between marijuana and industrial hemp.

Further, hemp is a strain of the *Cannabis sativa* plant that is grown primarily for use in industrial applications. It has been specifically cultivated to produce a low THC content and a high CBD content. The major health qualities of sativa medicinal strains are purported to be anti-anxiety, anti-depressant, chronic pain treatment, increased focus and creativity, and increased serotonin (a neurotransmitter involved in the regulation of learning, mood, sleep, anxiety, and appetite).

CBD has good health properties and is being incorporated in dietary supplements, foods, oils, and other products. Growers are compensated by how much CBD is in the hemp plant, so they are trying to grow plants with high levels. However, as CBD levels increase, so do THC levels. THC content cannot be more than 0.3% though.

These are just some of the many analytical challenges being faced.

Through CASP, AOAC can provide analytical solutions through a complete and harmonized quality system incorporating all AOAC programs. CASP is a forum where stakeholders can reach consensus on science-based problems, such as product/commodity-specific guidelines, speciation, and best practices. In addition to standards that lead to methods, AOAC provides training, proficiency testing, consulting services, sampling plans, validation guidelines, method certifications, publication projects, special meetings, and more. AOAC offers multiple forms of deliverables to meet specific analytical needs.

Initial Focus of Work

Food and Food Products

Consumption of cannabis products is legal and/or becoming legal in a growing number of U.S. states and in Canada. Consumable products include beverages, brownies, butter, chews, cookies, gummies, honey, edible oils, and more. AOAC is beginning the CASP activities with a focus on food and food products. Potential areas for the development of *Standard Method Performance Requirements* (SMPRs[®]) and methods include accuracy in label claim potency and/or public safety issues, such as detection of pathogens and/or residual solvents. SMPRs may address standards for screening methods that may eventually become *Performance Tested Methods*SM (PTMs).

Hemp

With the passage of the Agriculture Improvement Act of 2018 (commonly known as the farm bill), the hemp-derived CBD market is projected to increase from about \$591 million in 2019 to \$22 billion by 2022. AOAC plans to also focus on development of SMPRs and methods for accurate measurement of CBD in hemp plants, intermediate CBD ingredients, and/or dietary supplements, as well as determination of CBD in pet foods.

AOAC Forms Working Groups on Cannabis

In the initial phase, CASP will leverage AOAC's stakeholder infrastructure and standards development process to:

Cannabis-Related AOAC Official MethodsSM and SMPRs[®]

*Official Method*SM **2018.10** Cannabinoid in Dried Flowers and Oil

*Official Method*SM **2018.11** Quantitation of Cannabinoids in Cannabis Dried Plant Materials, Concentrates, and Oils

AOAC SMPR 2017.001 Cannabinoids in Cannabis Concentrates

AOAC SMPR 2017.002 Cannabinoids in Dried Plant Materials

AOAC SMPR 2017.019 Cannabinoids in Chocolate

AOAC SMPR 2018.011 Pesticides in Cannabis

"Clarification of Testing Materials" (AOAC guidance document, www.aoac.org > Standards Development > SPSFAM > SMPRs)

*Official Methods*SM and *Standard Method Performance Requirements* (SMPRs[®]) are available on e-OMA at www.eoma.aoac.org. ■

- Develop a series of SMPRs for cannabis and hemp
- Issue Calls for Methods for each of the completed SMPRs
- Create expert review panels (ERPs) to evaluate candidate methods submitted in response to SMPRs and Calls for Methods

Initial priorities were identified during the launch of CASP at the AOAC Midyear Meeting. Based on these priorities, AOAC in May 2019 formed working groups for CASP to begin standards development activities:

- Working Group on Microbial Organisms in Cannabis and Hemp: Co-chaired by **Patrick Bird** (PMB BioTek Consulting) and **Julia Bramante** (Colorado Department of Public Health and Environment)
- Working Group on Contaminants in Cannabis and Hemp: Chaired by **Susan Audino** (Audino and Associates)
- Working Group on Cannabinoids in Cannabis and Hemp: Chaired by **Holly Johnson** (American Herbal Products Association)

Working groups are developing standards for analytical methodology used to measure cannabinoid levels and chemical contaminants in marijuana and hemp plant materials, and to detect pathogens in cannabis.

Working Group on Microbial Organisms

In May 2019, the Working Group on Microbial Organisms reached consensus to focus on *Aspergillus* to start. *Aspergillus* is much more commonly found in cannabis than *Listeria monocytogenes* or *Salmonella* species. The working group agreed to adopt and adapt current food microbiology method evaluation guidelines, which will require many samples, but will help build credibility with the food community.

Working Group on Contaminants in Cannabis and Hemp

On May 3, 2019, the working group agreed to revisit the issue of pesticide detection. A subgroup was formed to look at AOAC SMPR 2018.011 (Identification and Quantitation of Selected Pesticide Residues in Dried Cannabis Materials). The subgroup is organizing a team of 3–5 laboratories to try to meet the SMPR and provide data on appropriate action levels.

Working Group on Cannabinoids in Cannabis and Hemp

The working group met on May 6, 2019, and reached consensus to focus on creating an SMPR for cannabinoids quantitation in hemp plant materials. The working group discussed the possibility of developing a white paper on how to calculate and report THC content in various materials, specifically with methods that measure THC and THCA separately.

Draft SMPRs will be posted to the AOAC website for an open comment period. All comments received will be reviewed and reconciled, if necessary, by AOAC and working group chairs.

The next CASP meeting is scheduled for September 7, 2019, at the

133rd AOAC Annual Meeting and Exposition in Denver, Colorado, USA, at which time it is expected that draft SMPRs will be reviewed for approval. If approved, AOAC will issue Calls for Methods for each SMPR. Standards developed by the working groups will be used to evaluate candidate laboratory methods submitted to AOAC's rigorous PTM and *Official Methods of Analysis*SM (OMA) programs. It is planned that AOAC ERPs will evaluate candidate methods against approved SMPRs in March 2020.

In addition to reviewing SMPRs during the 133rd AOAC Annual Meeting, CASP members will identify the second set of priorities for working groups. ■

Join Us

Join AOAC to provide solutions for regulators, industry, and consumers by developing globally accepted consensus-based standards and testing methods for hemp, cannabis, and cannabis-related ingredients/products. Contributors (see below) will participate in the development of standards for hemp and cannabis methods. These standards will then be used by method developers to develop methods, and by AOAC to evaluate methods so that resulting PTMs and OMAs are fully validated to the high standards of AOAC INTERNATIONAL and meet the analytical needs of the community. These AOAC-adopted reference methods will result in reliable data to support effective compliance-driven quality control of products and enhance public health.

For the CASP prospectus, visit www.aoc.org. For more information on CASP, to join a CASP working group, or to become a CASP contributor, contact **Scott Coates**, senior director, AOAC Research Institute, and CASP Program Lead, at scoates@aoac.org or Tel: 301-924-7077, ext. 137. ■

Initial Contributors (June 7, 2019)

CASP Pioneers

ABC Testing, Inc.	PathogenDx
Association of Food and Drug Officials	PerkinElmer
Bia Diagnostics	R-Biopharm AG
Bio-Rad	SCIEX
GW Pharmaceuticals	Supra Research and Development
Industrial Laboratories	TEQ Analytical Laboratories
Materia Medica Labs	Titan Analytical
MilliporeSigma	Trilogy Analytical

CASP Partners

CEM Corp.	Eurofins Scientific
CV Sciences	Trace Analytics

CASP Affiliates

Charm Sciences	Lazarus Naturals
Crystal Diagnostics	Medicinal Genomics
Hygiena	SC Labs
Institute of Food Technologists	