An Update to AOAC International Methods in the Cannabis Industry



Presented by: PJLA President, Tracy Szerszen Pat Bird of PMB BioTek Consulting

> Thursday, May 13, 2021 1:00-2:00 PM EDT



Presentation Overview

PJLA



Tracy Szerszen President Perry Johnson Laboratory Accreditation (PJLA) **17025 Requirements** regarding selection of appropriate methods

Overview of the work of AOAC Cannabis Analytical Science Program - CASP New Test Methods In the Industry

Questions & Answers



Webinar Housekeeping

- This webinar will be recorded
- All PJLA webinars are made available on our website & YouTube channel
 - https://www.pjlabs.com/training/

pjla-webinars/past-webinars

- All attendees are muted
- Please utilize the question tool bar to submit questions
 - To be answered at the end of presentation



PJLA

PJLA in the Cannabis Industry

- 100+ Accredited Cannabis Laboratories Globally
- Hemp and Cannabis Testing Labs -Both Medical and Recreational
- Typical Scopes
 - Potency
 - Residual Solvents
 - Pesticides
 - Heavy Metals
 - Mycotoxins
 - Water Activity
 - Filth and Foreign Matter
 - Microbiological
- Accredited First Cannabis Lab in 2014

ISO/IEC 17025:2017 - 7.2 Selection Verification and Validation of Methods

- Methods shall be appropriate for the test
- Methods shall be up to date and available to personnel
- Labs shall use the latest version of the method unless its not appropriate to do so
- It is recommended to select methods that are published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment
- In-house developed methods are also accepted
- Additional criteria required for validation of in-house methods

Possible Future State Regulator Expectations

- Laboratories may be required to use nationally recognized test methods available in the industry over time
 - Equal playing field between all labs
 - Consistent and reliable results
 - Possibly less review of data packages and monitoring by states
- As an accreditation body, PJLA is starting to see more labs in the industry participate in method studies and prepare to establish protocols in accordance with available methods
- We recommend all cannabis labs monitor industry changes

Welcome and Introductions



Guest Speaker: Patrick Bird PMB BioTek Consulting consulting@pmbbiotek.com

As the principal consultant at PMB BioTek Consulting, Pat works with method developers, contract laboratories and industry to identify solutions to emerging microbiological issues, optimizing method workflows and designing validation studies. Pat is an active member of the AOAC CASP initiative, previously serving as co-chair of the microbiology contaminants working group and is a co-conveyor for several projects within the Food Microbiology Method Validation Working Group (WG3) within ISO/TC34/SC9. Pat holds a BS in Microbiology from the Ohio State University in Columbus, Ohio and a MS in Food Safety from Michigan State University in East Lansing, MI.

Developing Standards, Validation Guidance and Educational Resources

The Role of the CASP in the Cannabis Community



About AOAC INTERNATIONAL

AOAC INTERNATIONAL brings together government, industry, and academia to establish standard methods of analysis that ensure the safety and integrity of foods and other products that impact public health around the world

- AOAC INTERNATIONAL publishes globally-respected standards that provide scientists and laboratories with consensus-driven, verified processes for food safety testing.
- AOAC INTERNATIONAL acts as a convener, bringing together experts to identify gaps in food safety testing and to create scientific standards that accurately and reliably fill those gaps.
- 360° approach to solving food safety issues.



In Food & Agriculture, We Set the Standard

History of AOAC

- Established in 1884 as the Association of Official Agricultural Chemists.
- Later, the Association of Official Analytical Chemists name was adopted to better reflect additional safety interest areas.
- Today, the organization's legal name is AOAC INTERNATIONAL, to reflect the global nature of its impact.
 - Long-form name: ASSOCIATION OF OFFICIAL ANALYTICAL COLLABORATION (AOAC) INTERNATIONAL
 - "In Food & Agriculture, We Set the Standard"

Scientific Standards Development







Develop a Program









Standards and Method Development Proficiency Testing

Training & Mentoring

Scientific Publications



Horizon-scanning

International Harmonization



Recruit Volunteers

AOAC will recruit key stakeholders from government, industry and academia



Develop Requested Output

- Standard Method Performance Requirements (SMPRs[®]) are voluntary consensus standards, developed by stakeholders, that prescribe the minimum analytical performance requirements for classes of analytical methods.
- Validation Guidelines
- Proficiency Test Samples
- Training and Education

AOAC SMPR[®] 2020.002

Standard Method Performance Requirements (SMPRs[®]) for Detection of Salmonella species in Cannabis and Cannabis Products

Intended Use: Consensus-Based Reference Method

1 Purpose

AOAC SMPBs describe the minimum recommended performance characteristics and suggested inclusivity/exclusivity organisms to be used during the evaluation of a method. The evaluation may be an on-site verification, a single-laboratory validation, or a multi-site collaborative study. SMPBs are written by AOAC working groups which are composed of representatives from industry, regulatory organizations, contract laboratories, test kit manufacturers, and academic institutions. AOAC SMPBs may be used for method development and optimization. Additionally, AOAC SMPRs are used by AOAC expert review panels in their evaluation of validation study data for methods being considered for *Performance Tested Methods*¹⁰ or AOAC Official Methods of *Analysis¹⁰⁴* and can be used as acceptance criteria for verification at user laboratories.

2 Applicability

Alternative methods used to detect *Salmonella* species and their serovars in cannabis and cannabis products. 3 Analytical Technique

Any analytical technique that can meet the requirements

4 Definitions

Candidate method.—Method submitted for validation. [Appendix J: AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Methods and Methods of Analysis and Environmental Surfaces, Official Methods of Analysis of AOAC INTERNATIONAL (2019) 21st Ed., AOAC INTERNATIONAL, Rockville, MD, USA]

Candidate method confirmed result.—Final result obtained for a test portion after cultural confirmation of a candidate method. Candidate method presumptive result.—Preliminary result for a test portion produced by following a candidate method's

instructions for use. *Cannabis.*—Genus of flowering plants within the Cannabinaceae

family that commonly contain ⁹-4etralydrocannabinol (THC), cannabidiol (CBD), and other cannabinoids and terperes. Cannabis includes, but is not limited to, high-THC and high-GBD cultivars. *Cannabinois andico terpeness*) manufactured through the extraction cannabinois and/or terpeness) manufactured through the extraction and concentration of compounds derived from the cannabis plant or flower. Final products can be many forms, including oils, wax, or hash (Category II).

Cannabis-infused edibles.—Food and drinks containing extracts of cannabis and/or cannabis materials (Category III).

Cannabis-influed nonedibles.—Products containing extracts of cannabis and/or cannabis materials intended to be applied to the human body or any part thereof. Final products can be many forms including creams, ointments, cosmetics and therapeutic pads (Category IV). Cannabis plant and flower.—General terms for the structural and flowering unadulterated parts of the cannabis plant (Category I). Cannabis products.—Products (edible and nonedible) extracted or infused with compounds derived from the cannabis plant including but not limited to CBD and THC.

Exclusivity.—Study involving pure nontarget strains, which are potentially cross-reactive, that shall be not detected or enumerated by the candidate method. See Table 1 for a list of recommended committee Guidelines for Vialdution of Microbiological Methods for Food and Environmental Surfaces, Official Methods of Analysis of AOAC INTERNATIONAL (2019) 21st Ed., AOAC INTERNATIONAL, Reckville, MD, USA)

INTERVISIONER, ROSPILE, NUMERIE, WILL, USAY, USAY,

Inchaining.—Study involving pure target strains that shall be detected or enumerated by the candidate method. See Tables 2 and 3 for a list of recommended target strains. [Appendix J: AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Microbiological Methods for Pood and Environmental Surfaces, Official Methods of Analysis of AOAC INTERNATIONAL (2019) 21st Ed., AOAC INTERNATIONAL, Rockville, MD, USA] Laboratory probability of detection (IPOD).—POD value obtained from combining all valid collaborator data sets for a method for a ziven matrix at a ziven analyte level or concentration.

method for a given matrix at a given analyte level or concentration. [Appendix H: Probability of Detection (POD) as a Statistical Model for the Validation of Qualitative Methods, Official Methods of Analysis of AOAC INTERNATIONAL (2019) 21st Ed., AOAC INTERNATIONAL, Rockville, MD, USA] LCL.—Lower confidence limit.

Probability of detection (POD).—Portion of positive analytical outcomes for a qualitative method for a given matrix at a given analyte level or concentration. Difference in POD values between presumptive and confirmed results is termed dPOD_{CP}

Salmonella .-- Straight rods, 0.7-1.5 × 2-5 µm. Gram negativ Usually motile by peritrichous flagella. Facultative anaerobic Chemoorganotrophic, having both a respiratory and fermentative metabolism. D-glucose and other carbohydrates are catabolized with the production of acid and usually gas. Oxidase negative, catalase positive, indole and Voges-Proskauer negative, methyl red and Simmons citrate positive. Lysine and ornithine decarboxylase positive, there is a variable arginine dihydrolase reaction. H,S is produced, urea is not hydrolyzed, and growth on KCN and utilization of malonate are variable. Reduce nitrates. Carbohydrates usually fermented include L-arabinose, maltose, D-mannitol, D-mannose, L-rhamnose, D-sorbitol, trehalose, and D-xylose, Occur in humans, warm- and cold-blooded animals, food, and the invironment. Pathogenic for humans and many animal species. Causative agent of typhoid fever, enteric fevers, gastroenteritis, and septicemia. [Bergey's Manual of Determinative Bacteriology, 9th Ed., John G. Holt (Ed)]

Test portion.—Sample size used in most validation studies. For cannabis flower/plant and cannabis inflused nonedible products, a 10 g test portion is used. For cannabis concentrates, a 5 g test portion is used. For cannabis-inflused edibles, a 25 g test portion is

2020 AOAC INTERNATIONAL

Standard Method Performance Requirements

- Standard Method Performance Requirements
 (SMPRs[®]) are voluntary consensus standards,
 developed by stakeholders, that prescribe the minimum
 analytical performance requirements for classes of
 analytical methods.
- SMPRs are unique to AOAC's processes and were introduced in recognition of the fact that acceptance criteria are critical to evaluating the suitability of any testing protocol for its intended use.
- Objective to develop an SMPR for quantitative methods for the enumeration of yeast and mold (and other analytes)



PMB BIOTEK CONSULTING



The Scientific Association Dedicated to Analytical Excelle

Official Methods of Analysis of Adac International

21st Edition, 2019

Volume I

Editor Dr. George W. Latimer, Jr.

Conformity Assessment: *Official Methods of Analysis*SM

AOAC INTERNATIONAL's premier methods program.

- Approved methods undergo rigorous, systematic scientific scrutiny to ensure they are highly credible and defensible and can be used with confidence by industry, regulatory agencies, research organizations, testing laboratories, and academic institutions.
- OMA methods are recognized in the U.S. Code of Federal Regulations and are legally defensible in court worldwide.
- The program is designed to evaluate chemistry, microbiology, and molecular biology methods.
- These methods include
 - Traditional benchtop methods
 - Instrumental methods
 - Proprietary, commercial, and/or alternative methods.



Conformity Assessment : *Performance Tested Methods* & *Review and Recognized*



- Assists companies and their customers safeguard their businesses, mitigate risk, and protect consumers through trusted, reliable testing methods and products.
- Provides independent third-party review and certification for proprietary test method performance.
- The certification mark assures users that an independent assessment found that test method performance meets an appropriate standard for its intended use
- Can be the first step toward Official Method[™] status
- Proprietary microbiology and chemistry methods and instruments
- >300 certified methods



Emergency Response Validation Program

- Designed to respond immediately to emerging food contamination crises by rapidly evaluating candidate methods in a single validation study.
- Brings together experts from government, academia and industry to develop consensus validation outline.
- Independent laboratory component incorporated into study design
- Recently engaged to detect
 - SARS-CoV-2 on environmental surfaces
 - Total yeast and mold in cannabis flower



Scientific Standards Development





Pioneer Members

ABC Testina Applied Food Sciences Association of Food and Drug Officials (AFDO) BioRad **GW** Pharmaceuticals Ionization Labs Materia Medica Laboratories

MilliporeSigma PerkinElmer R-Biopharm AG SõRSE Technology SupraRnD **TEQ** Analytical Titan Analytical

Partner Members

CV Sciences **Deibel Bioscience** **Eurofins Scientific**

Affiliate Members

Alkemist Labs **BIOTECON Diagnostics** Canopy Growth Corporation **CEM** Corporation **Charm Sciences**

Crystal Diagnostics Hygiena Institute of Food Technologists (IFT) Medicinal Genomics SC Labs

Cannabis Analytical Science Program

► Launched in 2018

Initiative is to develop analytical tools for accurate measurement of analytes in cannabis and hemp materials

https://www.aoac.org/scientific-solutions/casp/



Cannabis Analytical Science Program

- 11 SMPRs Developed and Approved.
- 2 Official Methods of Analysis (2018.10; 2018.11)
- 6 PTM micro methods
- 7 methods in TYMC
 Project
- 1 Salmonella in testing
- 1 STEC in testing
- 2 Aspergillus in testing



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Five Working Groups

Cannabinoids in Consumables

Chemical Contaminants

Microbiology Contaminants

Training and Education

Proficiency Testing

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Standard Method Performance Requirements

Microbiology

- 2019.001 Detection of Aspergillus in Cannabis and Cannabis Products
- 2020.002 Detection of Salmonella species in Cannabis and Cannabis Products
- 2020.012 Detection of Shiga Toxin-Producing Escherichia coli in Cannabis and Cannabis Products
- 2020.013 Mycotoxin Screening Technique in Cannabis Plant Material and Derivatives
- Draft SMPR Quantitation of Total Yeast and Mold in Cannabis and Cannabis Products

Chemistry

- 2017.001 Quantitation of Cannabinoids in Cannabis Concentrates
- 2017.002 Quantitation of Cannabinoids in Dried Plant Materials
- 2017.019 Quantitation of Cannabinoids in Edible Chocolate
- 2018.011 Identification and Quantification of Selected Pesticide Residues in Dried Cannabis Materials
- 2019.002 Identification and Quantitation of Selective Residual Solvents in Cannabis Derived Materials
- 2019.003 Quantitation of Cannabinoids in Plant Materials of Hemp
- 2020.001 Determination of Heavy Metals in a Variety of Cannabis and Cannabis Derived Products

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Chemistry Validation Guidance

Analytes

Matrixes

System Suitability

Reference Materials/Guidelines

Analytical Techniques

Performance Requirements

Microbiology Validation Guidance

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Inclusivity & Exclusivity Requirements

Categorization of Matrices

Inoculum Preparation

Equilibration/Stabilization

Cultural Confirmation

Cannabis and Cannabis Infused Product Categories



Category	Minimum Test Portion Size, g ^a
Plants & flowers	10
Concentrates	5
Infused edibles	25
Infused non-edibles	10







Validated Methods

PTM Certified Methods

- GENE-UP AspergillusPRO
- GENE-UP Salmonella 2
- GENE-UP EHEC
- iQ-Check Aspergillus
- iQ-Check Salmonella II
- iQ-Check STEC VirX

PTM Data Collection

• PathoSEEK 5-Color Aspergillus Multiplex

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 Detect^x (Salmonella, STEC & Aspergillus Multiplex)

OMA Certified Methods

- 2018.10 Cannabinoids in Dried Flowers and Oil
- 2018.11 Quantitation of Cannabinoids in Cannabis Dried Plant Materials, Concentrates, and Oils Liquid Chromatography–Diode Array Detection Technique with Optional Mass Spectrometric Detection

WHERE TO FIND VALIDATED METHODS

https://members.aoac.or g/AOAC/PTM Validate d Methods.aspx



AOAC Research Institute Search *Performance Tested Methods* SM

To obtain a test kit or validated method, please contact the Manufacturer directly.

*Don't know the criteria? Click "**Find**" for a full listing of validated methods.

*ANALYTE
*MATRIX
*MANUFACTURER
*KIT NAME
*LICENSE
Find

Please enter your search criteria to view results



WHERE TO FIND METHODS

eoma.aoac.org





Reference Materials

- Proficiency Testing working group is coordinating the preparation of reference materials
- Chaired by Dr. Walter Brent Wilson, NIST
 - Coordinates the <u>CSD Cannabis research</u> program at NIST
 - Developing *Cannabis* reference materials
 - Quality Assurance Program (CannaQAP).
- This Working Group is managed by the AOAC Laboratory Proficiency Testing Program to provide a seamless transition to our community once they are ready.

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Training and Education

- **Training and Education** (T & E) working will identify needs of the cannabis community and seek opportunities to collaborate with other training and education programs.
- Webinars
 - Developing Standards and Method for the Detection of Aspergillus in Cannabis and Hemp Materials
 - AOAC Emergency Response Validation for Total Yeast and Mold in Cannabis Products (Part 1 and 2)
 - CASP WEEK (Available on AOAC Website)
 - MJBiz/Analytical Cannabis West
- <u>Partnerships</u>
 - Hemp and Cannabinoid Science
 Institute (HCSI)
- <u>ALAAC/TDLM</u>



AOAC Workshops





Method Validation





Questions???

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PJLA

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