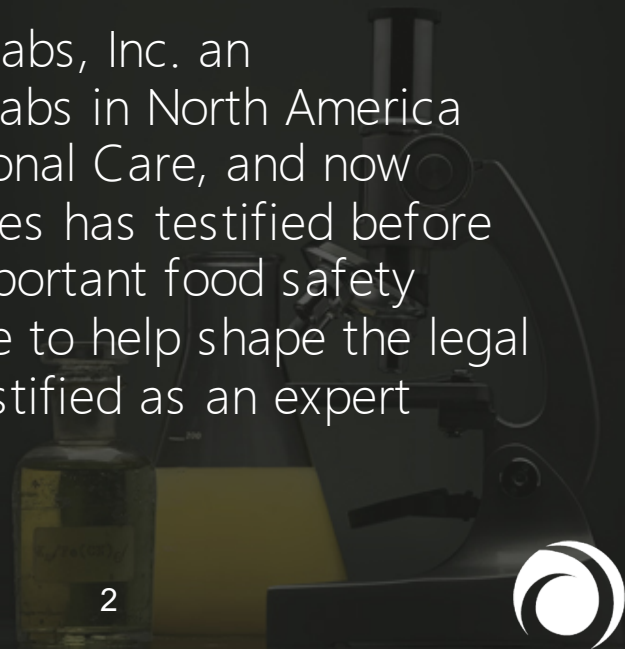
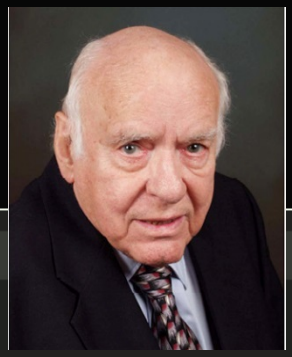
The Evolution of the Lab Testing Market: A History of Food & Cannabis Lab Testing – How Far We've Come

Cannabis Industry Journal. Food Labs / Cannabis Labs Virtual Conference, June 2-5, 2020

Deibel Labs was founded by Dr. Robert Deibel in the 1960s. Deibel Labs has witnessed firsthand the evolution of laboratory testing. This presentation will include a discussion of the history of food and cannabis testing, how far we've come as industries and where we're heading. It will also include a discussion about the intersection between food testing and cannabis testing, how the industries have evolved, and how the industries continue to work to protect patient and consumer safety.

Charles Deibel is the President and CEO of Deibel Labs, Inc. an internationally recognized corporation of 15 testing labs in North America for over 50 years, serving the Food, Beverage, Personal Care, and now Cannabis Industries. As an industry advocate, Charles has testified before the House Energy and Commerce Committee on important food safety concerns. He worked with the Department of Justice to help shape the legal case against Peanut Corporation of America and testified as an expert witness during the trial.





Dr. Robert Deibel – Founder

One of the "Founding Fathers of HACCP"; expanded HACCP from it's original 3 principles to 5 and started the Industry's first "HACCP Short Course", teaching HACCP to the Industry outside of Pillsbury

ALSO:

- Developed the first commercial "Rapid" pathogen assay (Salmonella).
- Developed media (M-Broth) for *Salmonella* testing – STILL USED TODAY!
- Developed the first commercial starter culture (production of fermented sausage) at AMI.
- Pioneered food safety research with *C. botulinum* in cured meat products and uncured poultry products.
- Isolated, characterized and named a new enterococcus species, *Streptococcus avian*. Began working with this organism as a "Salmonella Surrogate" we still use today in certain Process Validations
- Authored or co-authored 87 peer reviewed journal articles, book chapters and research papers (*Laboratory Analysis of Milk and Dairy Products,* Bergey's Manual, Journal of Applied Microbiology, and many others… .).

Agenda

- A Brief History of Specifications
- Role of a Contract Laboratory - What does an Ideal Partnership Look Like?
- The Age of Standardization
- Forging Ahead – Consistency and Building Trust

A BRIEF HISTORY OF SPECIFICATIONS IN US

Brief History of Specifications in the US

Human civilizations have always formed around access to safe drinking water. It stands to reason that during the early 1900's, the first defined microbial specifications (Coliforms) were for drinking water.

- Age of Industrialization - large movements away from rural areas and into crowded urban centers, where diseases spread quickly.
- Coliforms – easy to test for; relative inexpensive, and fast.

The first specifications in foods were in milk; the Pasteurized Milk Ordinance, or PMO

- 1908 - First Health Departments established in US
- 1914 - First specification – Coliforms used as index for water quality
- 1924 - First food specification – Coliforms used as for milk quality

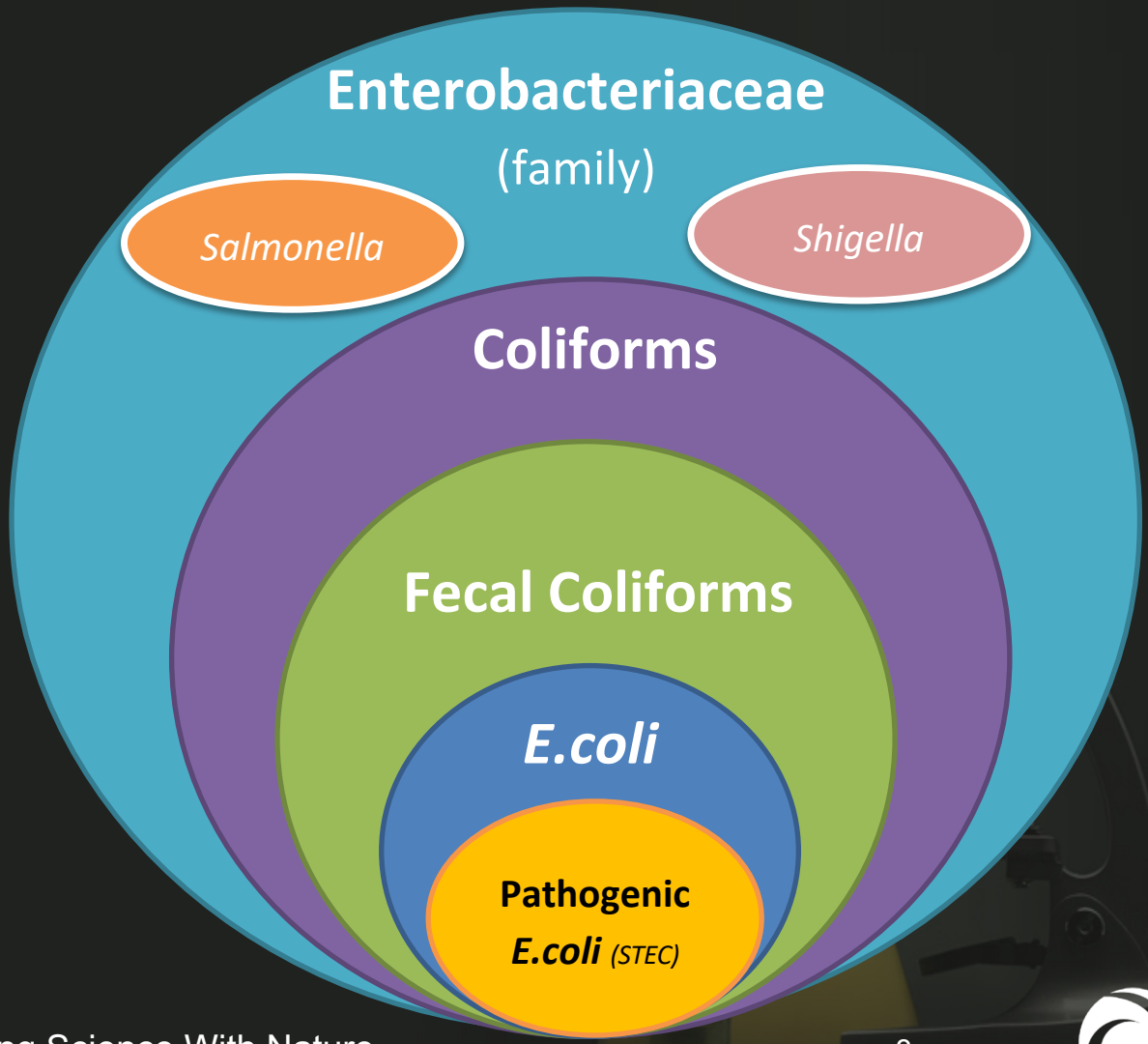
Coliforms

- So why was there a focus on Coliforms how did these help to guarantee safe water and milk?
  - Coliform bacteria are relatively simple to identify
  - present in much larger numbers than the respective pathogens
  - react to the environment and various antimicrobial interventions similarly to pathogens (i.e. Salmonella and E.coli).
  - Coliforms are bacteria that are always present in the digestive tracts of animals, including humans, and are found in their feces (thererfore good "indicator organisms").

How this all looks

Remember back to High School Biology (Kingdom, Order, etc… .). The "EBs" are the family of many pathogen bacteria.

Coliforms are not taxonomically defined, but if they were, they would looks like this:

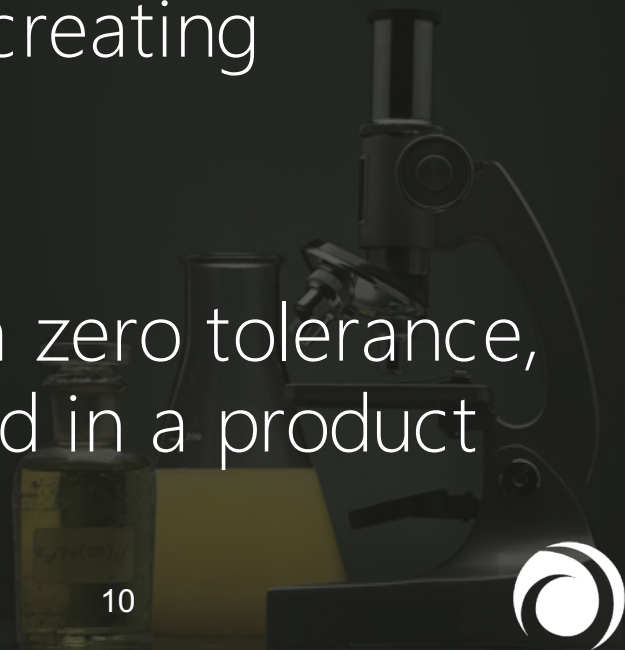


How to Interpret Coliform Data

- Coliform bacteria are a commonly used bacterial indicator of the sanitary quality of foods and water;
  - A typical result is (<10/g in processed foods or <500/g in cannabis)
- In the food Industry, we use coliforms as indicators of (thermal) process control, proper sanitation, and overall plant hygiene.
- If there is a surge in coliform activity, then "*SOMETHING HAPPENED*".
  - The data is telling us that something went wrong somewhere and either the process (i.e. manufacturing plant) or the raw ingredient supplier needs to be investigated.

Pathogens – zero tolerance

- As previously discussed, Indicators "Indicate" something that can be wrong; dig deeper to investigate
- Pathogens = literally "Patho" or Greek pathos, meaning to misfortune, or condition and "Gen" meaning genesis or creation. So, "creating misfortune".
- Pathogens cause illness.
- Most pathogen specifications are a zero tolerance, meaning there can not be any found in a product



"Indicators" versus "Pathogens"

INDICATOR ORGANISMS		PATHOGENIC ORGANISMS	
ORGANISM	WHAT DOES IT MEAN?	PATHOGEN	WHAT DOES IT MEAN?
Coliforms	Used to indicator poor hygiene practices, poor process control (i.e. inadequate cooking), or poor sanitation practices	Salmonella, STEC E.coli, C.sakazakii (infant pathogen) are the most common analog to Coliforms.	All of these pathogens have a zero tolerance in the US. Most pathogenic forms have the potential to cause severe illness, sometimes leading to death. Their presence in foods, and cannabis products, will result in a recall.
E.Coli (generic)		Shiga-Toxin Ecoli (STEC)	These E. coli produce TOXINS that will make even healthy adults very sick, leading to long term effects, and in rare cases, death. There are many different types in this group, but "travelers diarrhea" is a common one
S.aureus	Skin! Or contact with foods/materials that have come from the skin, such as Milk.	Some S.aureus can produce a toxin (Staph EnteroToxin)	The toxin will make healthy adults very sick, but symptoms will ameliorate after the toxin is expunged from the body.
Yeast & Molds	Closely associated with WATER and AIR QUALITY.	Toxigenic Molds (i.e. Aflatoxins are the most common)	These toxins can make you sick, especially Aflatoxins which are VERY POTENT CARGINOGENS!

CONTRACT LABORATORIES

History of Contract Labs in the US

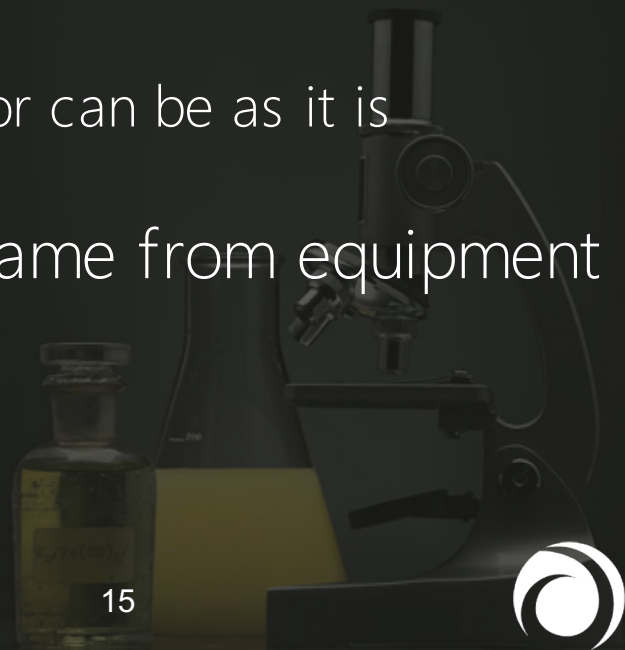
- Before the 1960's, the concept of a "Contract Lab" didn't exist.
- 1960's - Three main Food Testing Contract Lab organizations started about the same time: ABC Research, Silliker and Deibel.
- All three labs had vastly different business goals:
  - Dr. Bill Brown started ABC with the goal to become the industry's top "Research Lab". He would host a popular annual research summit. ABC Research remained a single lab facility in Gainesville, FL.
  - John Silliker wanted to build the largest lab testing organization. Silliker acquired by BioMerieux and grew globally to attain this goal; 2015 name changed to Merieux Neutrasciences.

Why Focus on Food Labs?

- Most of the cannabis methods initially derived from food testing methods.
- Initially there were no "specific" or published methods for cannabis extracts and inhalable products
- In lieu of published methods, there were still no validated methods for cannabis products (i.e./kit manufactures have yet to fully validate their methods to FDA standards)
- I.e. Many States reference EPA 40 CFR Part 180 "Pesticide Residues in Foods". VERY stringent

Cannabis Methods – not Standardized

- Labs can all be ISO Accredited, using methods that they have "validated", but they still aren't all the same:
  - One pesticide equipment manufacture recommends using a 1:250 dilution for the extraction (i.e. instrument result x 250 = final COA)
  - Another pesticide manufacturer recommends using a 1:10 dilution
- This in and of itself can result is huge differences in quantifiable data.
  - The higher the dilution, the higher the error can be as it is magnified.
- Limits Of Detection (LODs) are not the same from equipment to equipment



Can ISO Labs Make Mistakes?

- Absolutely. ISO does not guarantee labs will not make mistakes
- ISO Accreditations = ensure compliance to set Quality Systems, and proper documentation to track errors
  - It leaves a lot of freedom for how to meet the standard.
  - One labs interpretation of a ISO standard can be greatly different than another labs interpretation
- Not all ISO is the same
  - Lab ISO Marketing - "Well my ISO is Better Than Their ISO"… .

When choosing a Lab

- Do you trust them?
  - Imagine lab relationship in the same way you talk to your doctor, therapist, or lawyer. If you don't inherently trust them, then don't use them!
  - BUT - are you cultivating an environment where the lab feels they can trust you and be honest with any issues they are facing? Trust works both ways.
- Is the lab responsive to your emails/phone calls?
- Are they transparent with their lab facility (i.e. offering tours), or issues they are facing?

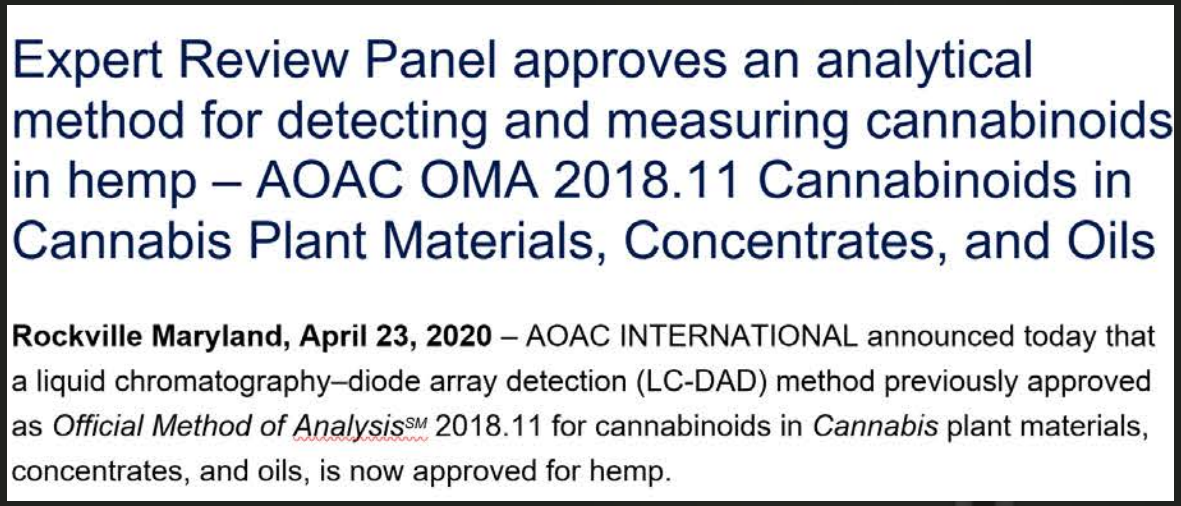
For the Cannabis Lab:

It's unfortunately still the wild west… .

ENTERING THE AGE OF STANDARDIZATION

It's a Brave New World! – AOAC OMA

The First Cannabis Methods are gaining the coveted "Official Methods of Analysis" approval.



Expert Review Panel approves an analytical method for detecting and measuring cannabinoids in hemp – AOAC OMA 2018.11 Cannabinoids in Cannabis Plant Materials, Concentrates, and Oils

Rockville Maryland, April 23, 2020 – AOAC INTERNATIONAL announced today that a liquid chromatography–diode array detection (LC-DAD) method previously approved as *Official Method of Analysis*℠ 2018.11 for cannabinoids in *Cannabis* plant materials, concentrates, and oils, is now approved for hemp.

First OMA Posted Cannabis Method (AOAC OMA 2018.11)!
October 2019 (Online Ahead of printed publication)
December 2019 (First Action publication)
January 2020 – OMA First Action on another Potency Method (2018.10)
May 2020 (Revised First Action 2020 for extension to hemp and to include a procedure for sample dry-weight determination)

The Road to AOAC Official Methods

- Experts Create Framework for Method
- Given a number ("SMPR 2017.001Cannabinoids in Cannabis Concentrates")

SMPR

Call For Methods (sometimes)

- Methods developers may also submit sole source/individual methods

- 8–10 laboratories participate in "Collaborative Study"
- Results published in journal
- Drafts, First Actions, and Revisions to First Actions

OMA First Action

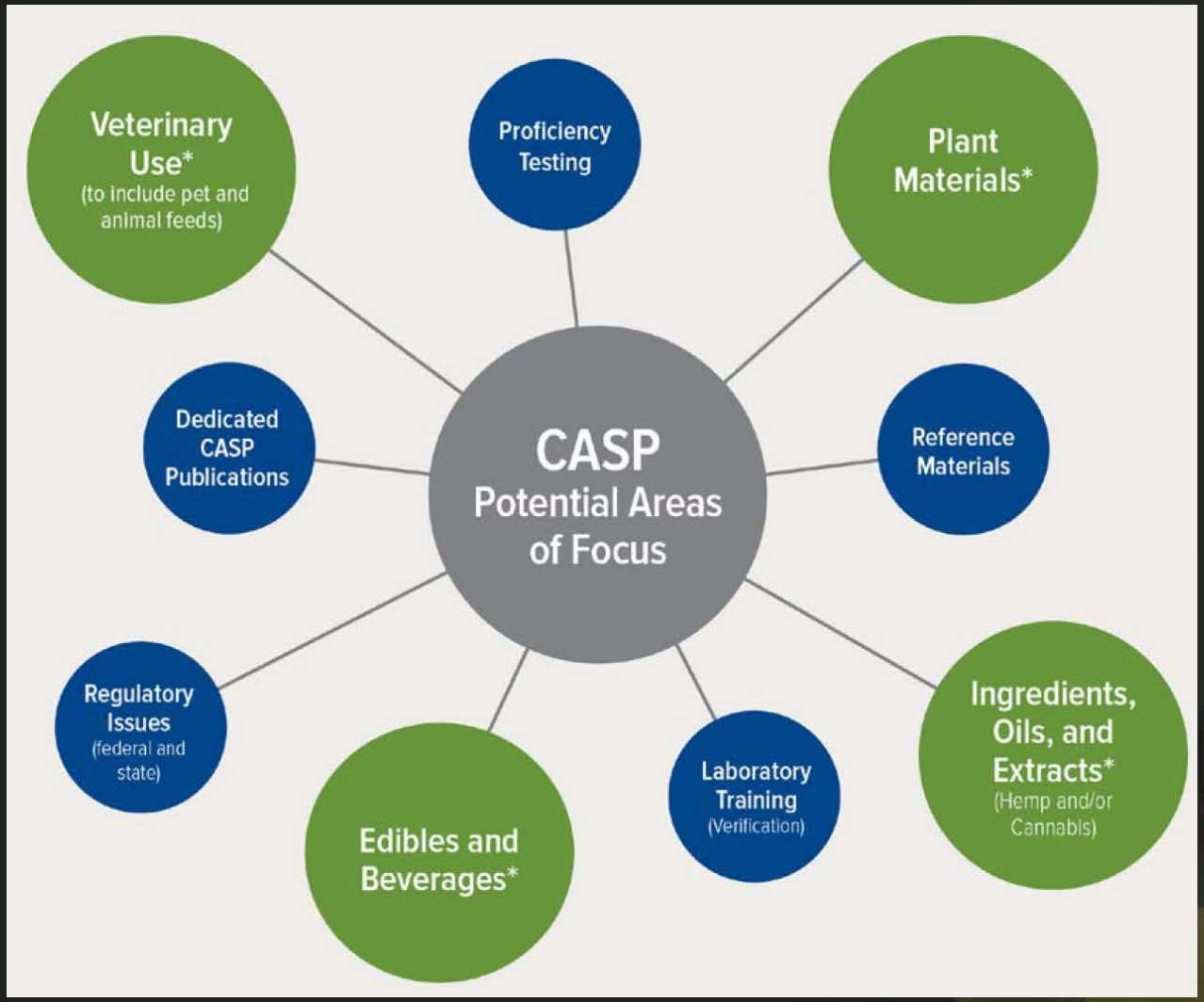
OMA Final Action

- Method is tracked for 2 years, ensure that different labs, equipment, personnel can all reproduce method

AOAC launches CASP (More Acronyms!)

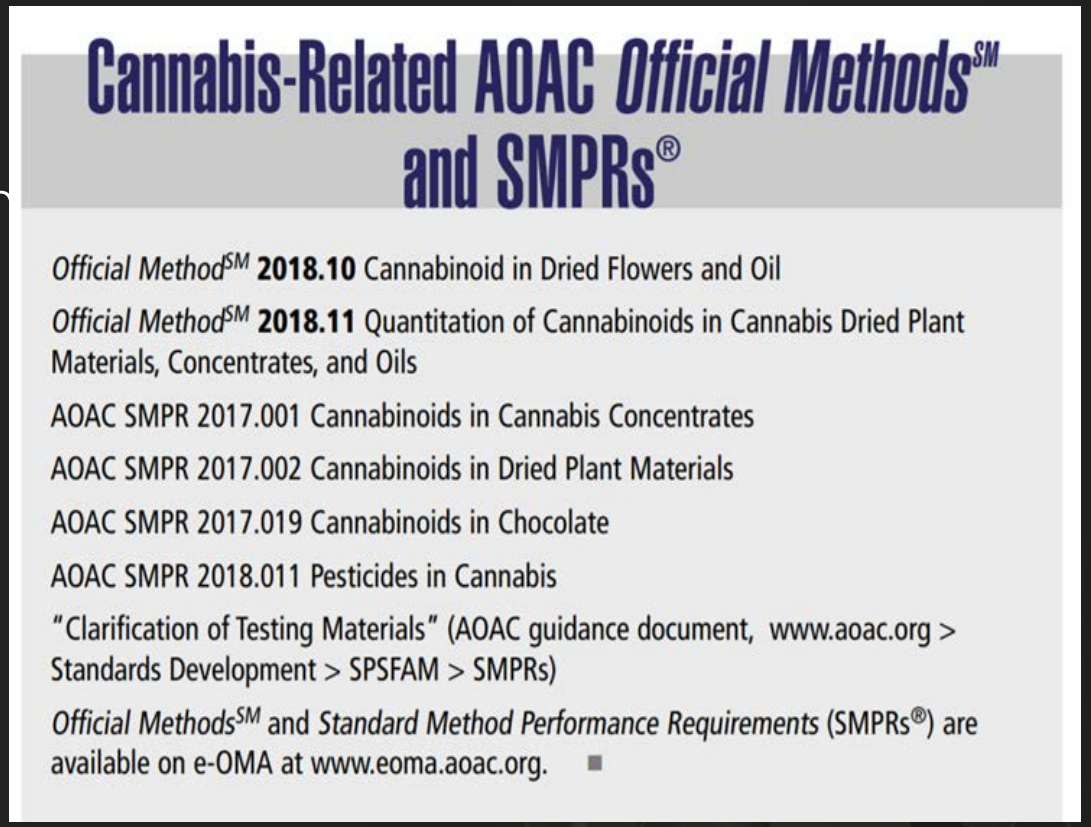
- AOAC developed the **Cannabis Analytical Science Program** (CASP) roughly March 2019 to:
  - provide both a scientific forum where the science of hemp and cannabis analysis can be discussed and
  - a mechanism for the development and maintenance of cannabis standards and methods.
  - AOAC cannot accept $ from Cannabis companies
- The CASP Advisory Panel formed three working groups in 2019 with analytical focus areas in:
  - microbiology, chemical contaminants, and cannabinoids in consumables.

CASP – At a Glance



Standard Method Performance Req's

- CASP FIRST established *Standard Method Performance Requirements* (SMPRs) in each analytical category.
- The SMPR's provide framework for testing since there are no reference standards for cannabis.
- CASP developed timeframes for each SMPR and Method



Cannabis-Related AOAC *Official Methods*℠ and SMPRs®

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

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

CASP Working Groups

AOAC/CASP Working Groups & Priority Subtopics		AOAC Programs			
		SMPRs	Methods of Analysis	Education & Training	Guidelines Accreditation Criteria
Microbiology	Aspergillus	**2019**	**2020**	**2020**	
	STEC	**2020**			
	Salmonella	**2020**			
	Listeria				
Chemical Contaminants	Pesticides	**2019**	**2020**		
	Residual solvents	**2019**	**2020**	**2020**	
	Heavy metals	**2020**			
	Mycotoxins				
Cannabinoids in Consumables	Hemp	**2019**	**2020**	**2020**	
	Personal Care				
	Concentrates & Oils		**2018, 2019, 2020**		
	Dry weight	**2019/2020**	**2018, 2019, 2020**		**2020**
	Veterinary products				
Education	TBD			**2020**	

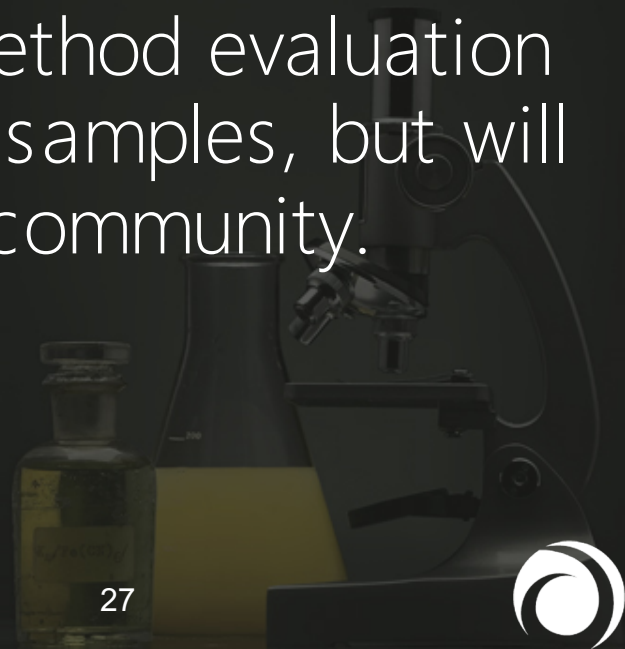
CASP Working Groups issued "Call for Methods". Expert Review Panels to review candidate methods with a goal of delivering *Official Methods* (First and Final Action).

AOAC 2018.11 – Potency's Path to Approval

- 2017 - Potency testing first started as "SMPR" frameworks in journal articles (not actual methods though):
  - AOAC SMPR 2017.001 (Quantitation of Cannabinoids in Cannabis Concentrates) *J. AOAC Int.* **100**, 1200(2017)
  - AOAC SMPR 2017.002 (Quantitation of Cannabinoids in Dried Plant Materials) *J. AOAC Int.* **100**, 1204(2017)
- 2018 – AOAC published a draft of 2018.11
- 2019 – Oct / Dec publish First Action of 2018.11
- 2020 – May – revision to include Hemp / Dry Weight calc's
- 2021-ish – Final Action (Methods must be shown to be reproducible before they are considered for Final Action, meaning that they perform consistently despite deviations in personnel, equipment, location and laboratory set up – First Action methods are tracked for two years before they become Final Action Methods).

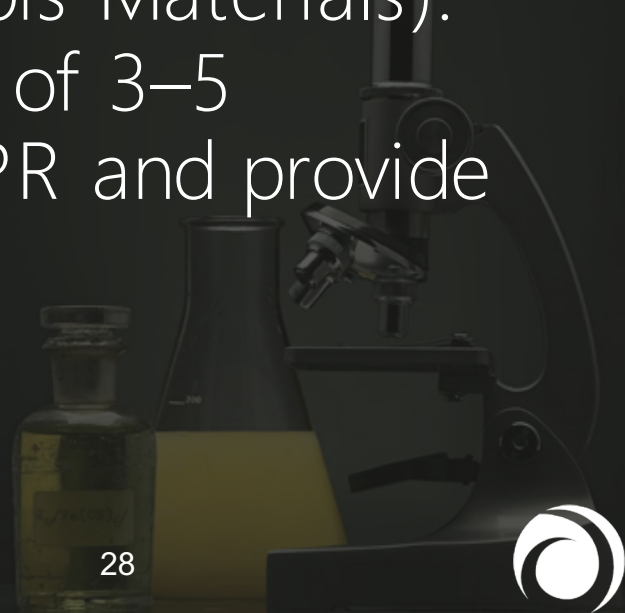
AOAC CASP - Microbial

- Working Group on Microbial Organisms. In May 2019, reached consensus to focus on Aspergillus.
- 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.



AOAC CASP - Contaminants

- 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.



Lab Testing in Cannabis

- The legality and acceptance of cannabis still new, labs have to function without the benefit of inter-lab collaboration or guidance from normal bodies that offer these published methods i.e. EPA, FDA, USDA, USP, etc.
  - Many cannabis companies will share their methods if they want to work with a lab
  - Most cannabis testing labs have to develop their own proprietary methods (from "application notes" from equipment companies).
  - Consequently these aren't shared in the industry.
  - We need standardized analytical methods that are published for everyone to use; product safety in cannabis is for everyone!
- The food safety industry has had decades to develop robust methodologies (i.e. AOAC OMA)
- BUT – even in food - we are still struggling with complex plant matrices, such as certain teas (cat nip, chamomile, etc).

FORGING AHEAD – CONSISTENCY & BUILDING TRUST

A Strong Focus on Regulations

- IN 2011, President Obama signed into the law the Food Safety Modernization Act (FSMA). The regulations were rolled out starting in 2017.
  - Largest overhaul of a government Agency in over 70 years!
- Cannabis Testing is also highly regulated, but at State levels, also rolling out concurrent to FSMA.
- BOTH INDUSTRIES = stronger focus around the legal implications of making safe products
- The role of lab testing (data accuracy), and the overall scrutiny on labs, is higher than ever.

The Labs' little secret….

Its (almost) all in the extraction step at the Laboratory… (this is different than cannabis extractions however)

- Even with published methods, Labs will all still develop their own procedures for the extraction phase – pulling out the chemicals for the instruments to measure.
  - Labs seek to optimize their methods, even from published methods, making them more robust & more efficient
  - Labs can have many methods for a given test, especially for Pesticides (i.e. flower, concentrates, edibles, etc).
- Assuming all other considerations are met, and all labs have robust equipment, validated SOPs and procedures, the extraction phase is the most important aspect of lab testing.

Sampling – Its all based on Statistics

There is no statistical validity in a sample size of 1!

The greater number of RANDOM subsamples, per Lot/batch, the better your chances of finding a contaminate.

- In Cannabis - ~0.2g-1.0g of flower / oil / edible is used for each required test (pesticides, cannabinoids, micro, etc).
- 1 gram is relatively small! In food, FDA mandates 750g (Salmonella)
- It is entirely likely that two different 1 g samples can have two different results, especially for flower.
  - Was the pesticide sprayed equally over every bud? No, probably not.
  - Is Aspergillus (mold) growing evenly on each leaf? No, probably not.

That is why it is imperative to take a random sample, by collecting several smaller samples from different areas of the entire batch.

Standardizing Potency

- When we look into the future, as a community we must deliver consistent potency data to our clients.
  - The larger organizations know how to manage their cultivation greenhouses, know how to keep out pests / heavy metals, and effectively manage pesticide use
  - What we hear, is they need consistency from the labs
  - Many edibles / concentrates clients have to over dose concentrates to ensure that any lab variability will still yield potency levels that meet Regulatory limits.
- Labs must develop more robust QC, as well as internal standards, for ensuring **EACH** Potency result is accurate.

In Conclusion:

The cannabis industry has had a rocky start; including having to matured rapidly under intense regulatory oversight. But as a relatively young industry we've come a long way!

In many ways, its still the Wild West, and there's still a lot of work to be done. But now we are seeing more help in having access to reliable standardized Methods.

And now, there are many competent, certified labs providing reliable data to producers and consumers.


DEIBEL
LABORATORIES
Thank You!
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