



AOAC INTERNATIONAL

An Update

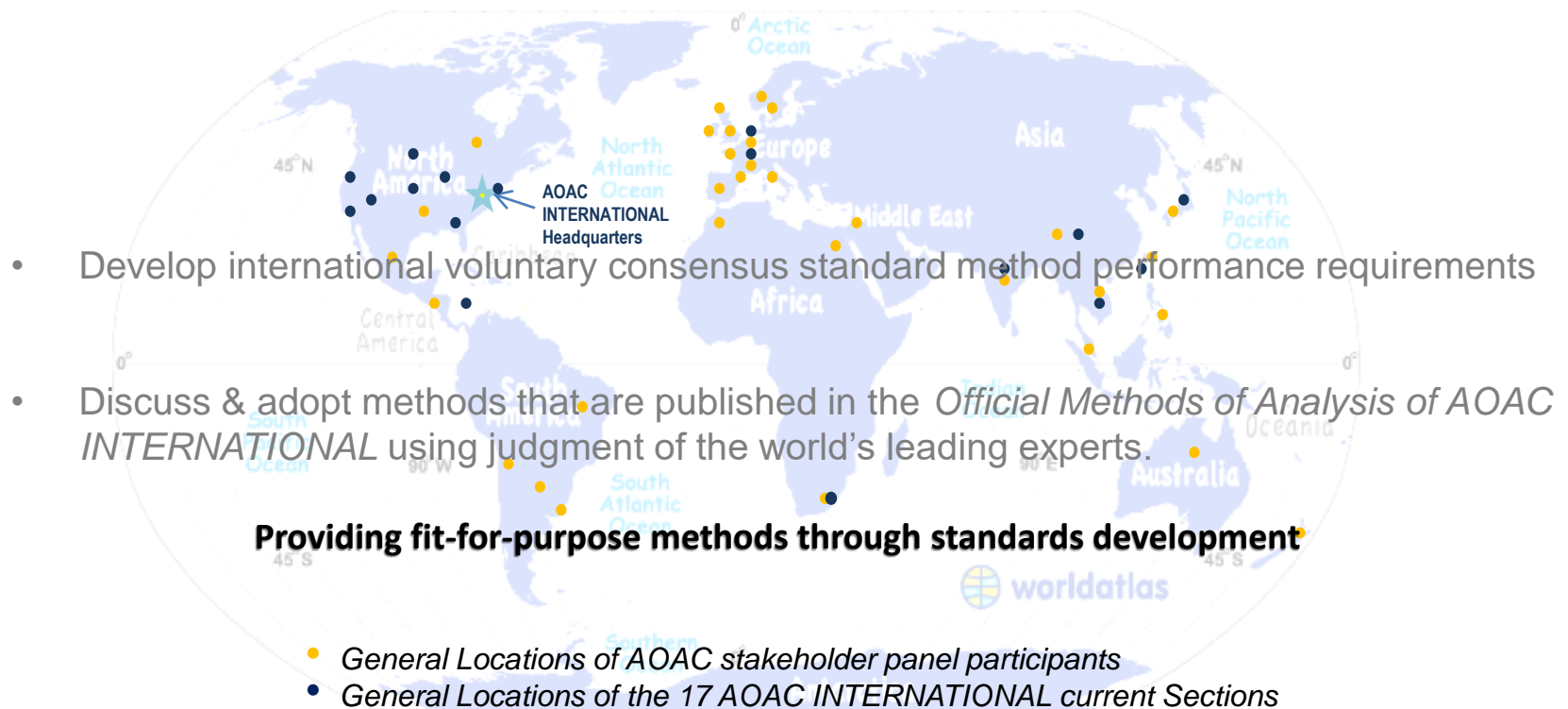
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AOAC Deputy Executive Director & Chief Science Officer

2019 AAFCO Annual Meeting
August 6, 2019

AOAC Leverages the *Power of Many*

AOAC Leverages Networks to Assemble Stakeholders & Experts



AOAC INTERNATIONAL's Strategic Goals

Analytical Excellence

Address emerging issues and influence standards development as a global leader in analytical excellence.

People

Attract and develop deeply engaged members, volunteers, staff, and customers to grow and strengthen the association and its programs.

Relationships

Build strategic partnerships to advance food safety, food integrity, and public health.

Core Programs

Develop and improve existing core programs, products, and services.

Sustainability

Identify, strengthen, and grow revenue streams to ensure the association's long-term sustainability.

Governance

Establish a highly effective governance and leadership culture providing value to all members and stakeholders.



The Past meets the Future

Our Roots and our Mission Remain Unchanged

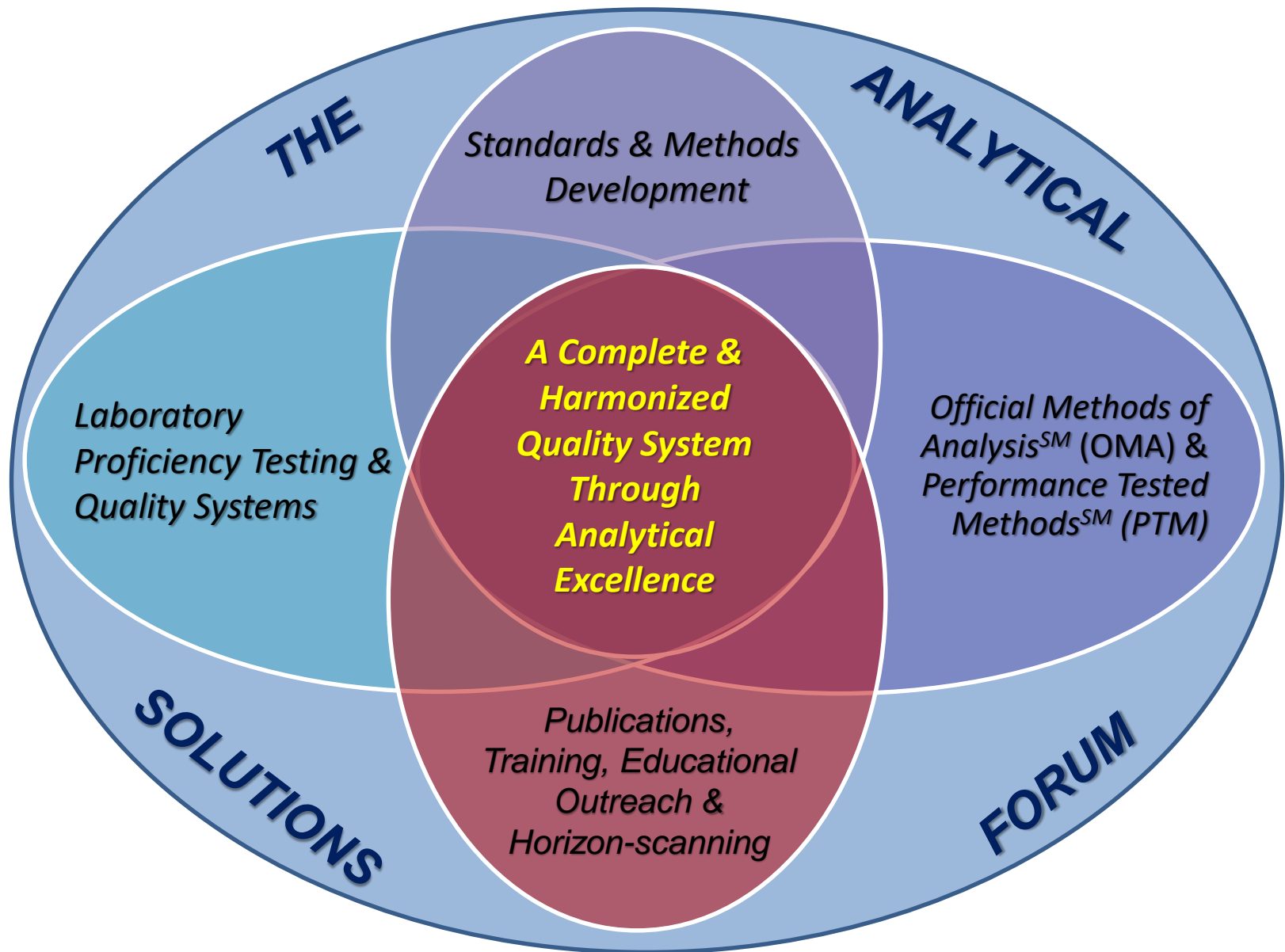
As a leader of analytical excellence, AOAC INTERNATIONAL advances food safety, food integrity, and public health by bringing together members, organizations, and experts dedicated to developing and validating standards, methods, and technologies of global relevance.

Our Future

Expanding our global leadership for our stakeholders by striving to integrate analytical excellence e.g. developing and validating standards, methods, and technologies with training and capacity building programs to foster complete laboratory quality systems.



The Past meets the Future



Why a “*FORUM*”?



“Forum”.....

*...A **place**, situation, or group in which people exchange ideas and viewpoints, discuss issues/current questions;*

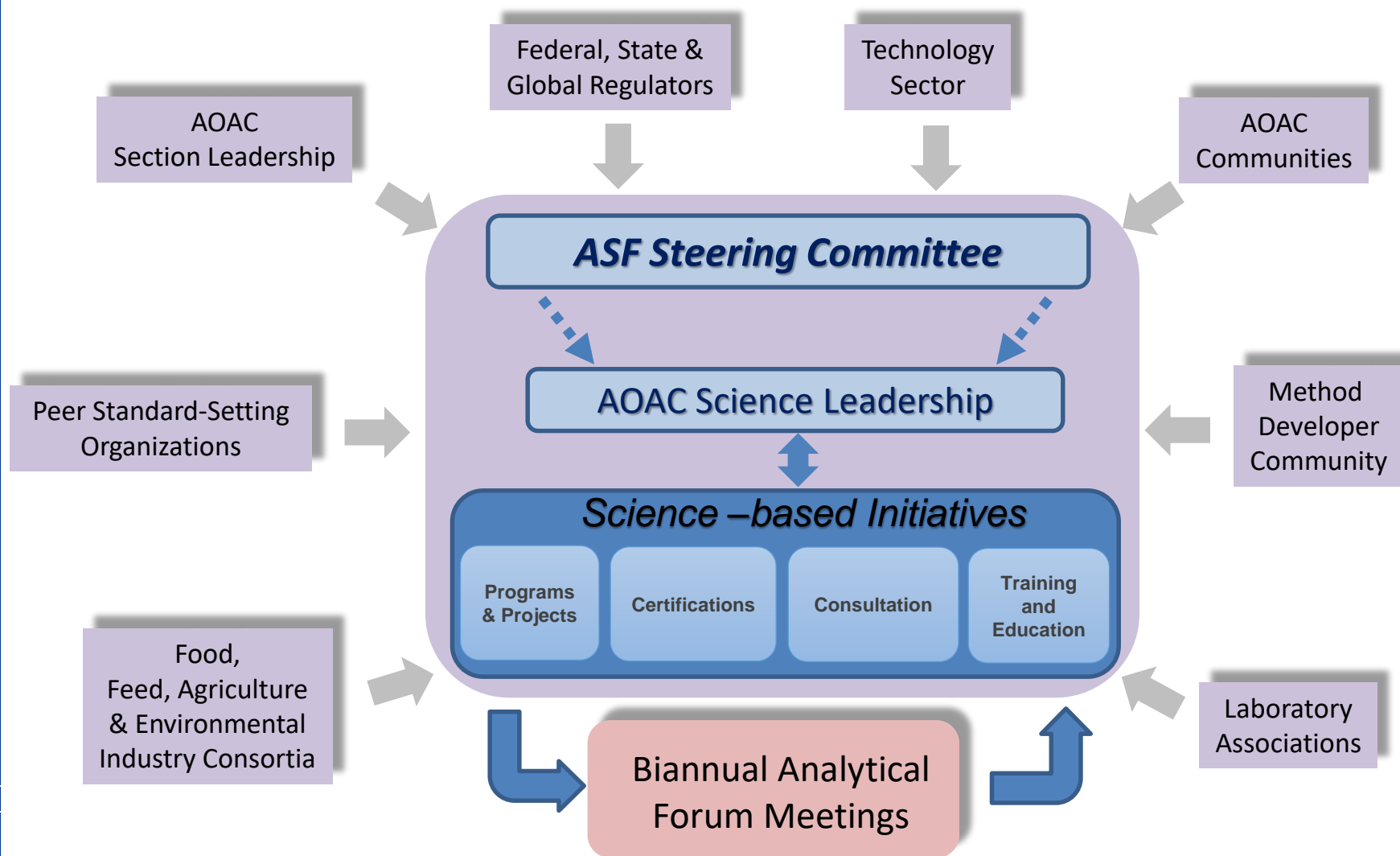
*...An **assembly**; a public meeting or lecture involving audience discussion;*

*...A **program** involving discussions of issues by authorities;*

*...An **opportunity** for open discussion to stimulate broad interest and encourage participation from multiple perspectives.*



The Analytical Solutions Forum Concept



The Analytical Solutions Forum

“To stimulate thought; to facilitate communication; to encourage participation”

- Multi-faceted “idea incubator”;
- An evolution of the current stakeholder panel model to expand services to the analytical, food, feed and agricultural safety communities;
- Broader Stakeholder input and engagement;
- Biannual forums;
 - *To provide updates from funded tracks;*
 - *A venue to focus on regulatory and emerging issues.*
- Horizon scanning;
 - *Proactive; identify needs before public health emergencies arise;*
 - *To develop new scientific programs and foster technological advancements to meet arising challenges.*

The Analytical Solutions Forum provides...

- Multiple avenues to identify new programs or new deliverables; a continuous stream of scientific ideas and potential funding opportunities to accomplish the work;
- A mechanism to integrate, prioritize and provide oversight to prospective and ongoing programs and projects;
- Programs funded on an annual, renewable basis;
- Multiple forms of deliverables;
 - *Standard Method Performance Requirements*
 - *Method review*
 - *Sampling plans, validation guidelines*
 - *Harmonization, training/workshop development, proficiency testing*
 - *Consulting service*
 - *Method certification, publication projects, special meetings*

Flexibility for the Future

- Work within the parameters of the defined need?
Project or Program?

Project

A short term effort to deliver a specific output(s) in line with a predefined time, cost, and quality constraints; based on an agreed-upon work plan.

Program

A portfolio comprised of multiple projects that are managed and coordinated as one unit to achieve the expected outcomes determined by the advisory panel members; considered a long-term (potentially permanent) activity overseen by an AOAC INTERNATIONAL-designated Program Lead and Scientific Advisory.

- Individual stakeholder engagement or Advisory Panel “Scientific Crowd-sourcing”

Addressing opportunities and provide products and services not defined or confined by existing stakeholder panels.

The Analytical Solutions Forum

Supplements
SPDS

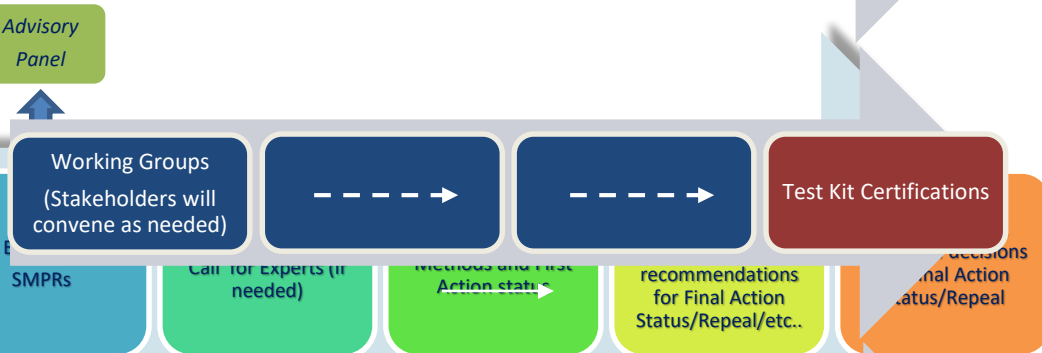
Infant Formula and
Adult Nutritional
SPIFAN

Strategic
Analytical
SPS
and "The
PANEL"

Advisory
Panel



Advisory
Panel



Advisory
Panel

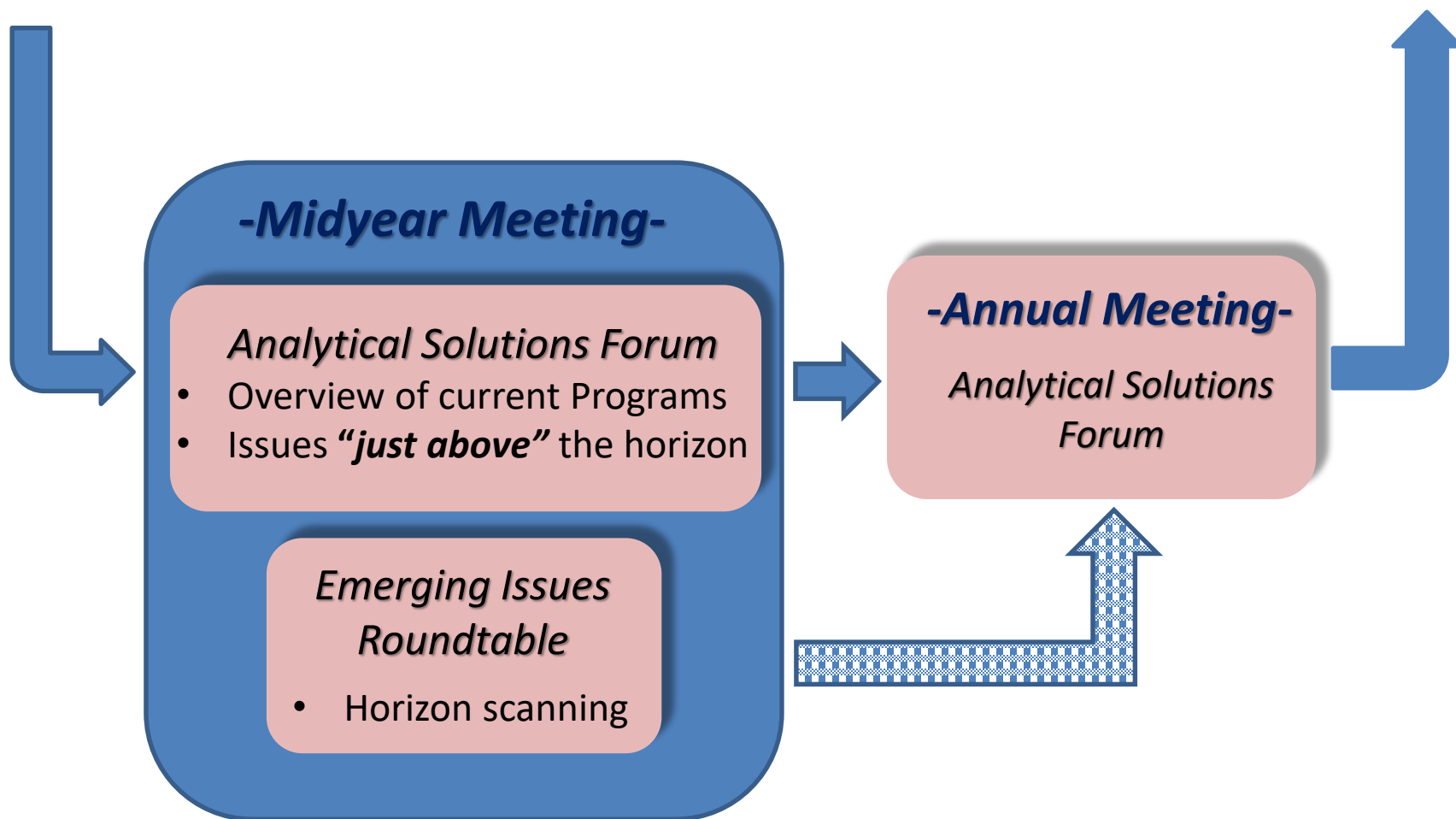


Advisory
Panel



The Analytical Solutions Forum

Continuity Between Midyear and Annual Meetings



The 2019 Midyear Meeting & the Inaugural Analytical Solutions Forum...*The Transition begins*

Newly Launched Programs

Introducing New Organizations Development

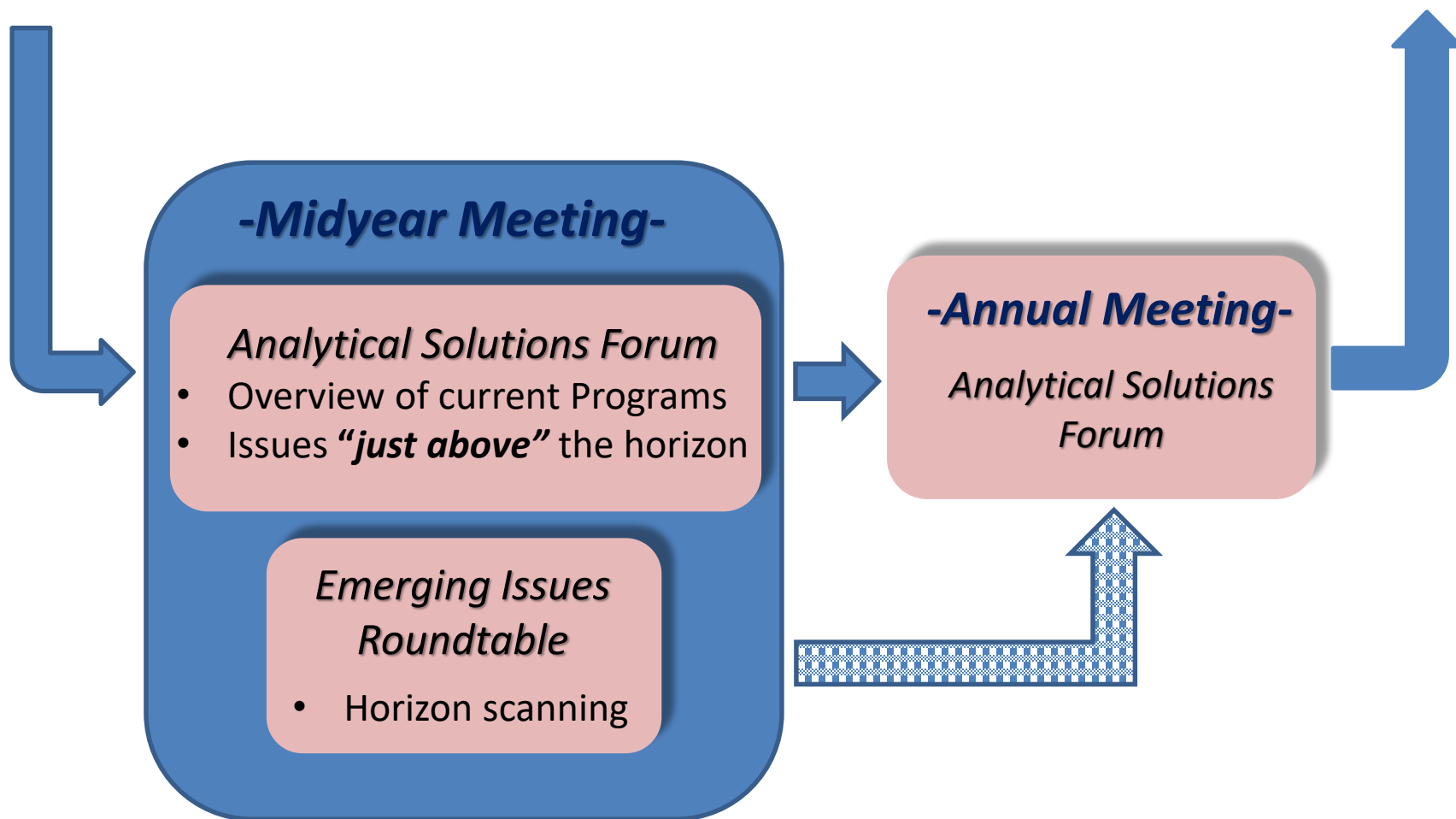


- On-site validation program
- Application note certification program
- Analytical science consultation services

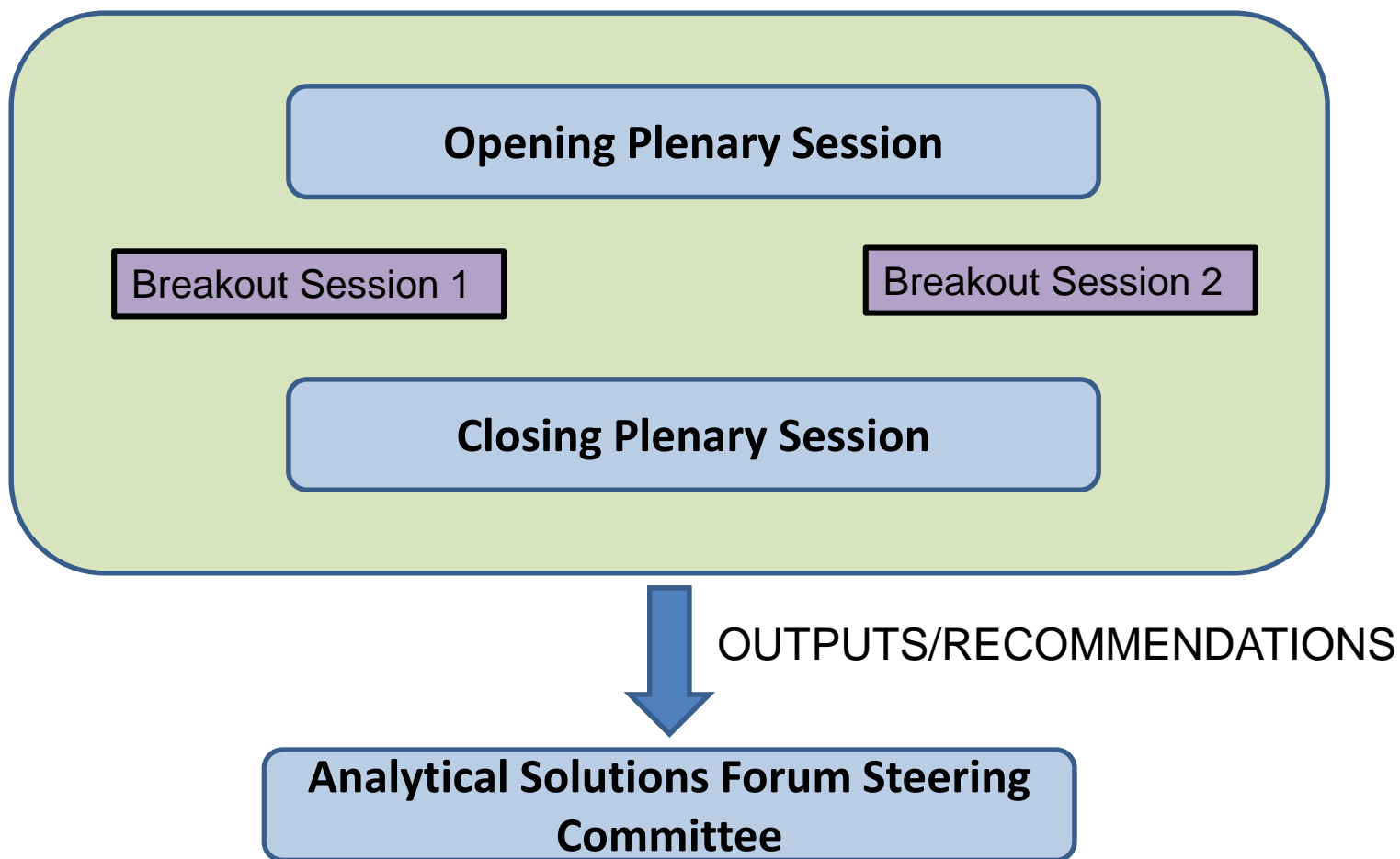


The Analytical Solutions Forum

Continuity Between Midyear and Annual Meetings



The Analytical Solutions Forum: *The Annual Meeting*



The 2019 ASF @ The Annual Meeting

“Analytical Tools for Emerging Agricultural Products”

Plenary 1 (0830-0945):

Introduction to the Annual Meeting ASF

- Inception of the forum topic
- Keynote Address 1: Botanicals and Herbal Supplements
- Keynote Address 2: Biostimulants and Soil Amendments
- Closing remarks: Objectives and expectations for breakout sessions

Breakout Sessions (1000-1200)

Informational lunch and learn session (1230-1300)

“ASF Concept 101”

Plenary 2 (1300-1430)

- Review of breakout session presentations
- Read-out of proposal(s)
- Open discussion
- Next steps



Cannabis Analytical Science Program

- In 2018, AOAC created a full-time, dedicated program to cannabis analytical science.
- The AOAC initiative under the new program and project paradigm,
- Funded and directed by the prioritized needs of an Advisory Panel.



casp

Cannabis Analytical Science Program
PROSPECTUS



CASP Objectives

- Facilitate a forum where the science of cannabis analysis can be discussed.
- Provide a home for the development and maintenance of cannabis standards and methods.
- Identify reference materials.
- Establish a proficiency testing program.
- Provide analytical and laboratory management training, in particular ISO accreditation training.

Leveraging its extensive heritage 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 INTERNATIONAL — At a Glance

AOAC's history is intertwined with the development of food safety science in the US:

- Formed in 1884 at USDA, later part of FDA, AOAC became independent in 1970s
- Leader in Standards Development
- Global Trade Facilitator
- International Member Base
- Consensus Builder
- Official Methods of Analysis Publisher
- Academic, Industry & Regulatory Collaboration
- Laboratory Proficiency Testing Program



Cannabis-Related AOAC Standard Method Performance Requirements:

- SMPR 2017.001**
Cannabinoids in Cannabis Concentrates
- SMPR 2017.002**
Cannabinoids in Dried Plant Materials
- SMPR 2017.019**
Cannabinoids in Chocolate
- SMPR 2018.011**
Pesticides in Cannabis

CASP

Designed to include all of AOAC's expertise:

- *Standard Method Performance Requirements*
- *Performance Tested Methods (PTM) and Official Methods*
- *Laboratory operating recommendations*
- *Proficiency Testing program*
- *Reference materials (TDRM)*
- *Training workshops*
- *Journal Publications*



CASP Objectives

- Facilitate a forum where the science of cannabis analysis is discussed with international experts,
- Facilitate the development and publication of cannabis and hemp-specific methods and standards,
- Develop cannabis and hemp reference materials,
- Establish a cannabis and hemp proficiency testing program in accord with International Standards,
- Provide analytical and laboratory management training, in particular ISO accreditation training,
- Provide resources and education to regulators responsible for establishing rules and laws around cannabis and hemp.

AOAC Cannabis Projects Prior to

CASP

2015:
Symposium

“What’s the Buzz
about Cannabis”

2016: Cannabis
Advisory Panel

SCIEX, SPEX, CEM
GW Pharmaceutical,
SC Labs,
Sigma Aldrich

2017: Cannabis
Working Groups

- * Identification and Quantitation of Cannabinoids in Dried Flower
- Identification and Quantitation of Cannabinoids in Concentrates
- Identification and Quantitation of Cannabinoids in Chocolate
- Identification of Pesticide Residues in Dried Flower

2018: First Action
Methods

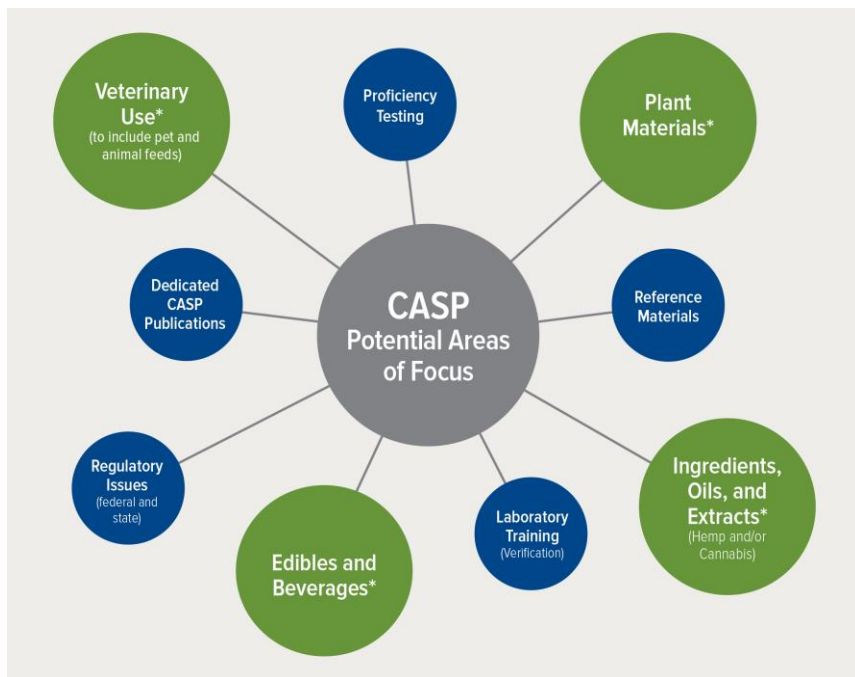
- Identification & Quantitation of Cannabinoids in Dried Flower
- Identification & Quantitation of Cannabinoids in Concentrates

Three Working Groups have Been established:

- Chemical contaminants in cannabis and hemp
 - Pesticides, toxic elements, mycotoxins, etc.
 - Review Target Limit of Quantitation for pesticides,
- Cannabinoids in consumables
 - Initial focus on cannabinoids in hemp plant materials.
 - Recommendation on reporting total THC (THC + THCA)
 - Recommendation on dry weight.
- Microbial pathogens and spoilage microorganisms
 - Initial focus on *Aspergillus*
- Additional considerations:
 - Education and outreach



CASP Specific Objective: *Long Term*



Targeting cannabis- and hemp specific standards and/or methods of analysis such as:

- potency
- pesticide residues
- biological contaminants
- chemical contaminants including select mycotoxins
- untargeted testing profiles
- method validation guidelines

Food Authenticity and Food Fraud

- *Food authentication**
 - a process to evaluate that state of being
- *Food fraud**
 - the act that creates the problem;
 - the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging; or false or misleading statements made about a product, for economic gain.

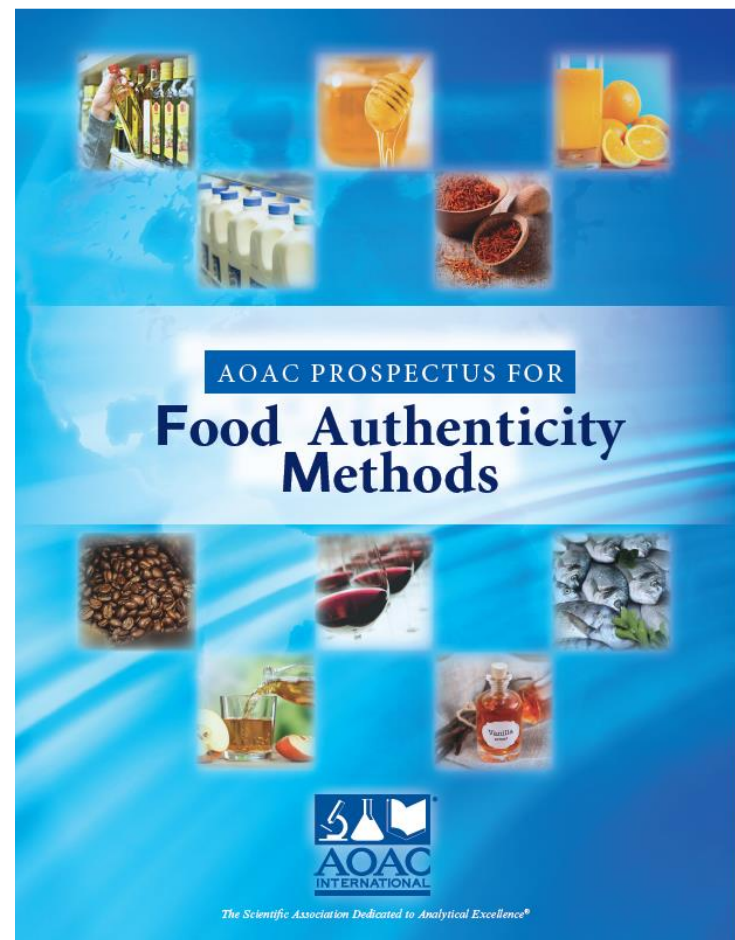
One of these things.....





Food Authenticity Program Objectives

- To address the analytical needs for combatting intentional and economically motivated food adulteration;
- Develop Standard Method Performance Requirements (SMPRs) for Targeted Testing (TT) and Non-targeted Testing (NTT);
- To develop rapid response guidance for method development in the event of an emergency.



Commodity Prioritization Survey

- Food Authenticity Advisory Panel was surveyed to determine
 - Which foods have a more immediate need for functioning and acceptable Non-Targeted Testing methods?
 - Which food/adulterant combinations do not have acceptable targeted analytical methods?

Non-Targeted Testing

- Concept
 - Create a standardized fingerprint for an ingredient.
 - Compare new lots of the ingredient to the fingerprint.
 - Quantify “degree of difference”
 - Small amount of difference is a yellow flag
 - Large difference is a red flag
- Create Standard Method Performance Requirements
 - Demonstration of Non-Targeted Testing method effectiveness
 - Validation/verification guidance
- Apply to NTT tests covering prioritized commodity list

Targeted Testing (TT)

- Targeted Testing (TT) requires the ***prior identification of adulterants*** likely to be present in priority food commodities, subject to EMA and is employed to assure that such adulterants is not threatening the safety and overall integrity of the priority ingredient
- Targeted Testing (TT) protocols/procedures to:
 - Support authenticity assurance
 - Ensure the food supply chain integrity
 - Convey the message to those engaged in those practices that they will be prosecuted.

Targeted Testing Working Group

- Assessment of gaps of current food fraud test method and develop SMPRs to validate targeted testing methods;
- Developing standards leading to Codex Type 1 methods;
- Prioritizing actions of adulterants and commodities of interest

Additional Topics

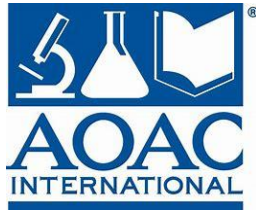
- Consider overlapping technologies for
 - targeted and
 - non-targeted testing procedures
- Recommend AOAC process for standards development and review, in the event of a major international food fraud incident, requiring rapid resource mobilization.

Where is AOAC INTERNATIONAL Going Next?

Revitalizing Efforts in Education & Training Outreach

- AOAC Annual Meeting
 - AOAC/A2LA Training Course – ISO/IEC 17025:2017 Bridging the Gap from 2005
 - Initially offered during Midyear Meeting
 - Sampling Training Course
 - Method Validation Course
- During the Spring and Summer
 - AOAC Analytical Methods Week – Expert Review Panels
 - SMPR Orientations
- AOAC is developing an overall curriculum that supports volunteers, customers, and members understanding
 - Multiple formats

Where is AOAC INTERNATIONAL Going Next?



A.I.M.S.

The Alternative International Methods and Standards Program

- Creation of “*Harmonized*” international validation standards; and, reference method and official method acceptance,
- Identification and updating out-of-date methods,
- OMA modification/extension needs and submissions,
- Method validation processes to support new versions of old methods,
- Affordability e.g. pilot programs to assess utility of PT data for validation needs.

Recognized Pain Points

- Expectations, costs and the return on investment,
- Balancing affordability without sacrificing quality and mission,
- Process rigidity,
- Timeliness and dedicated volunteer subject matter experts,

Closing Thoughts

Reaffirming that **COMMUNICATION** is key:

- Understanding the global and regional landscape,
- Partnering to address emerging issues, opportunities, and needs,
- Jointly developing the programs and resources needed to support and sustain AOAC's commitment to our regional and global stakeholders.

***The advancement of food safety,
food integrity and public health
through analytical excellence***

Contact Information

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THANK YOU