



The Latest on AOAC's Work on Botanicals and Dietary Supplements

ACIL P2 Meeting
March 29, 2023

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AOAC INTERNATIONAL

Overview



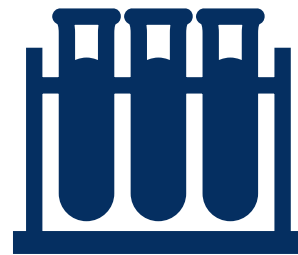
- About AOAC
- AOAC Science Programs
- AOAC & Dietary Supplement Community
- AOAC BIDS I Program
- Call to Action for Laboratories

AOAC'S ROOTS IN FOOD SAFETY



- ▶ 1884 - Association of Official Agricultural Chemists
 - ✓ Federal and state departments of agriculture through the USDA Bureau of Chemistry.
 - ✓ Initially to standardize methodology to be used for composition of fertilizers by state laboratories
 - ✓ Directed by Harvey Washington Wiley who wrote the 1906 law that began the US Food and Drug Administration (FDA)
- ▶ By the 1980s AOAC's membership included microbiologists, food science professionals
- ▶ In 1991, Association of Official Agricultural Chemists legally changed its name to AOAC INTERNATIONAL
- ▶ Association of Analytical Communities has been used to encompass all of the scientific disciplines involved in AOAC's work.
- ▶ Official name is AOAC INTERNATIONAL, but AOAC stands for Association of Analytical Collaboration

2023 – 2025 STRATEGIC PLAN

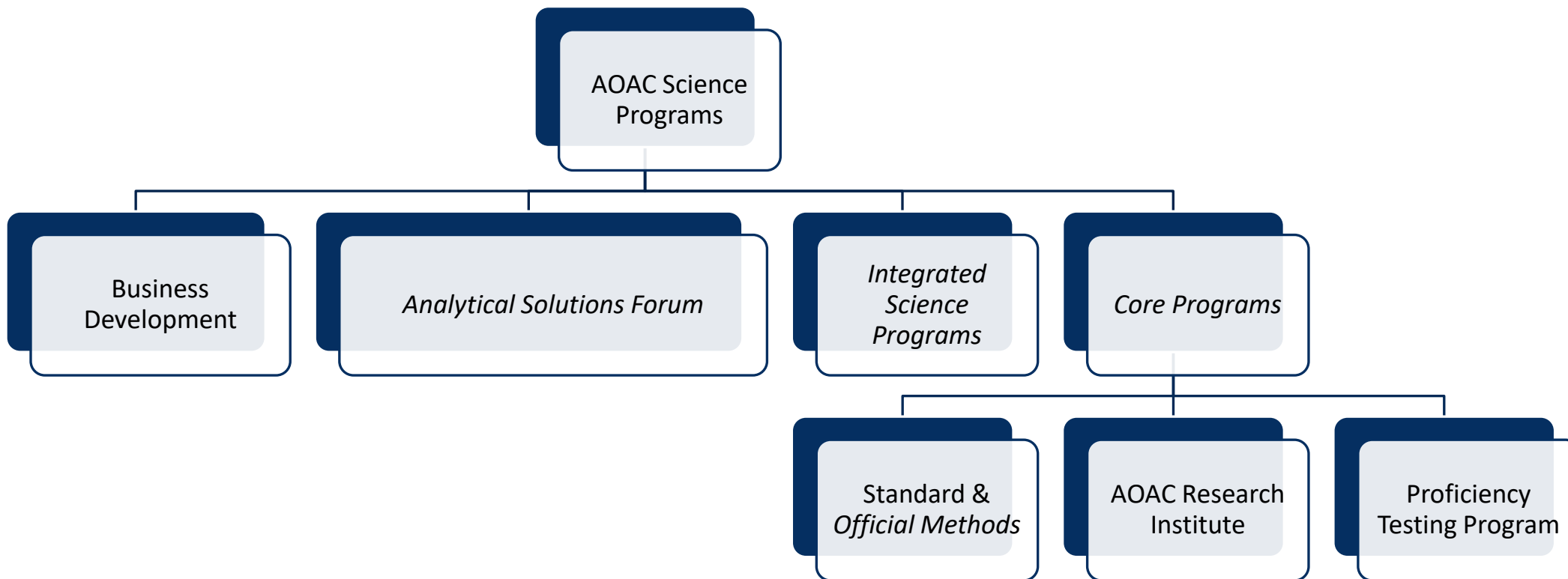


Vision: Global alignment for trusted analytical solutions

Mission: Advance food safety and product integrity through standards, validated test methods, and laboratory quality programs

Strategic Objectives: Growth, Relationships, and Integrity

AOAC SCIENCE PROGRAMS



AOAC's integrated science programs and projects are provisional activities formed under a specified thematic scope to achieve deliverables that incorporate services and expertise from each core program. The degree of program integration will vary based on the scope and need defined for the program or project.

AOAC's core science programs represent departments that serve as the foundation for all science activities and services

AOAC SCIENCE PROGRAMS – CORE PROGRAMS



- Address needs of analytical food & product communities
 - Regulatory requirements
 - Industry needs
- Custom PT programs for network of labs
- Accreditation Requirements
- Food Matrix PT
 - Chemistry, microbiology, pesticide residues, and vitamins/nutrients
- Environmental Swabs PT
 - Listeria and Salmonella
- Hemp & >0.3% low, med, high Δ -9-THC Cannabis PT



METHOD AND PROCESS CERTIFICATION



AOAC Research Institute
Installation &
Operational
Qualification



AOAC Research Institute
Reviewed &
Recognized





AOAC Research Institute
**Reviewed &
Recognized**

- ▶ New program from the AOAC Research Institute
- ▶ Certifies performance claims of application notes, user guides, or laboratory developed methods
- ▶ Based on the same method validation guidance and science required for *Official Methods* program
- ▶ Program requirements
 - ▶ In house validation
 - ▶ Independent verification to help support portability of the method

AOAC SCIENCE PROGRAMS – CORE PROGRAMS



AOAC Standards and Consensus Documents

- Method Performance Requirements
- Guidelines
- Sampling Standards
- Methods of Analysis
- Best Practice and Recommendations
- Operational Documents
- Reference Materials
- Training Documents

AOAC Standard Method Performance Requirements (SMPRs)

- Community agreement on the minimum performance requirements for a class of methods.
- Provide a logical way to define and detailed description of the analytical acceptance requirements
- Published as a standard and serves as a benchmark for method developers
- > 160 published

STANDARDS

Method Performance Requirements Infant Formula and Adult/Pediatric

Stakeholder Panel on Infant Formula and Adult/Pediatric Nutritionals (SPIFAN)

Version Date: April 5, 2011

Effective Date: April 5, 2011

Intended Use:

1. Applicability

Determination of total folate [supplemental folic acid (CAS 59-30-3) or 5-methyl-tetrahydrofolate (CAS 68792-52-9), and endogenous 5-methyl-tetrahydrofolate polyglutamate] in all forms (powders, ready-to-feed liquids, and liquid concentrates) of infant, adult, and pediatric nutritional formula.

2. Analytical Technique

Any analytical technique that meets the following method performance requirements is acceptable.

3. Definitions

Adult/Pediatric Formula

Nutritionally complete, specially formulated food, consumed in liquid form, which may constitute the sole source of nourishment (AOAC SPIFAN, 2010), made from any combination of milk, soy, whey, hydrolyzed protein, starch, and amino acids, with and without intact protein.

Infant Formula

Infant milk substitute specially manufactured to satisfy the nutritional requirements of infants during their first months of life, from the introduction of appropriate complementary feeding (WHO Standard 72-1981), made from any combination of milk, whey, hydrolyzed protein, starch, and amino acids, with and without intact protein.

σ (LOD)

Concentration or mass of analyte that can be detected with no greater than 5% false-positive risk.

Mass of analyte in a given matrix sample.

Test conditions constant during a short-term study.

Formula standard deviation (σ)

Recovery

The fraction or percentage of spiked analyte when the test sample is analyzed using the method.

4. Method Performance Requirements

Analytical range	0.50–300*	
Limit of detection (LOD)	≤0.10*	
Limit of quantitation (LOQ)	≤0.50*	
Repeatability (RSD _r)	0.50*	≤11%
	21.5*	≤7%
	43.0*	
	64.0*	
	85.0*	
Recovery	0.5	90–110%
	21.5*	
	43.0*	
	64.0*	
	85.0*	
Reproducibility (RSD _R)	0.5*	≤32%
	21.5*	≤16%
	43.0*	
	64.0*	
	85.0*	

Concentrations apply to (1) "ready-to-feed" liquids "as is"; (2) reconstituted powders (25 g into 200 g water); and (3) liquid concentrates diluted 1:1 by weight.

* $\mu\text{g}/100\text{ g}$ expressed as folic acid in reconstituted final product.

5. System Suitability Tests and/or Analytical Quality Control

Suitable methods will include blank check samples, and check standards at the lowest point and midrange point of the applicability range.

6. Reference Material(s)

NIST Standard Reference Material® (SRM) 1849 Infant/Adult Nutritional Formula, or equivalent. The SRM is a milk-based, hydrolyzed infant/adult nutritional powder prepared by a manufacturer of infant formula and adult nutritional products. A unit of SRM 1849 consists of 10 packets, each containing approximately 10 g of material.

Note: The reference value for NIST 1849 is 2.11 (± 0.13) mg/kg of folic acid. The performance parameters in this SMPR for folic acid and 5-methyl-tetrahydrofolate polyglutamate should be expected.

7. Validation Guidance

Recommendations

STANDARDS & SCIENTIFIC TOPIC CATEGORIES



Cannabis and
Hemp

Biological
Threat Agents

Botanicals and
Dietary
Supplements

Chemical
Contaminants
& Residues

Dairy

Food
Authenticity

Foodborne
Pathogens &
Indicators

Gluten and
Food Allergens

Heavy Metals

Infant formula

Meat, Poultry,
Fish, Seafood

Natural Colors

Natural &
Marine Toxins

Vitamin &
Nutrients

Oils and Fats

PFAS

Process
Toxicants

Novel Foods
(alternative
protein sources)

Surfaces and
Environmental
Matrixes

Botanical &
Dietary
Supplements

AOAC OFFICIAL METHODS OF ANALYSIS

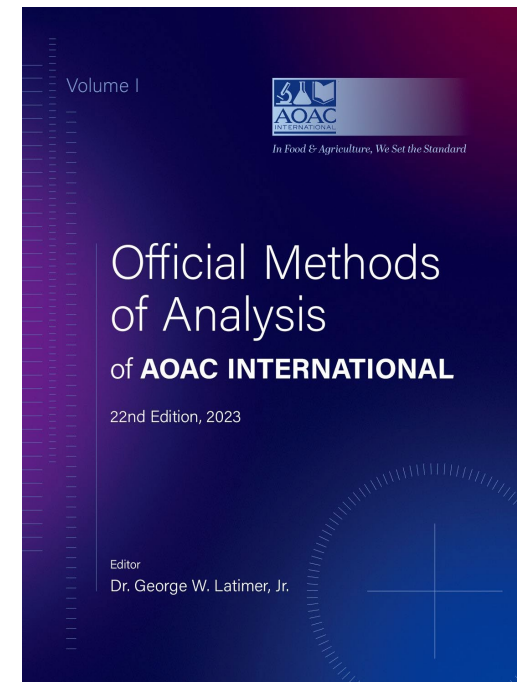


Why Are They Important?

AOAC methods are *scientifically valid* as specified in 21CFR111 cGMPs allowing manufacturers to adhere to comply with confidence

Consistency and reliability of test results for product in the market

Increased Reliability and Safety for the Consumer



CASE STUDY: METHODS NEEDED TO SUPPORT CONSENSUS-BASED APPROACH FOR COMPONENT SPECIFICATIONS IN BOTANICALS & DIETARY SUPPLEMENTS



Regulations: Globally multiple approaches

- Example: US - Good Manufacturing Practices
 - *Establish component specifications that are necessary to ensure that specifications for the purity, strength and composition of dietary supplements manufactured using the components are met,*
 - *Supplier Certificates of Analysis (COAs) of components; description of the test used and actual results of the tests or examinations.*

Standards and tools to support a consensus compliance

- AOAC published: 34 AOAC SMPRs for variety of target analytes
- *Official Methods (new chapter)* published: > 30 methods for various botanicals and dietary supplements
- Method Validation Training
- New section in AOAC Laboratory Accreditation Guidelines
- Dietary Supplement Community Forum

Public and private sectors:

- Subject matter experts and key opinion leaders from US government, global governments, **testing laboratories**, botanical & dietary supplement manufacturers, technology developers, food manufacturers.



ANALYTES COVERED IN 20 YEARS



Aloe Vera	Folin C	PDE5 Inhibitors
Aloin in Aloe	Free Amino Acids	Protein
Anthocyanins/Cranberries	Ginger	SAMe
Aristolochic Acid	Ginkgo	Saw Palmetto
Ashwagandha	Ginseng	Skullcap
Beta-Carotene	Glucosamine	St. John's Wort
Chromium	Kavalactones	Tea
Chondroitin	Kratom	Turmeric
Cinnamon	Licorice	Vitamin B6
Coenzyme Q10	Lutein/Zeaxanthin	Vitamin B12
Collagen	Lycopene	Vitamin D
Echinacea	Milk Thistle	Vitamin E
Ephedra	MSM/DMSO	Yohimbe
Folic acid (in 2022)	Omega 3	



- ▶ Began in 2022
- ▶ Develop performance standards applicable to the analyte (including dosages), component, contaminant, and matrix of highest priority.
- ▶ Instill confidence in test data reliability, for manufacturers, retailers, and regulators.
- ▶ Foster development and adoption of *Official Methods of Analysis* that are fit-for-purpose and apply appropriate, consensus-driven method performance standards to meet industry GMP requirements and regulatory review.

BIDSI - A FORUM FOR ANALYTICAL SOLUTIONS



BIDSI ADVISORY PANEL

Standards and Development

Component Analysis,
Multi- component
analysis

Agricultural Contaminants

Validation and
Verification Criteria

Authenticity and Integrity

Sampling

Reference Materials

Next Generation
technologies and
applications

Supply Chain Traceability

Education and Training

Manufacturers and Retainers

Method Developer

Training courses for single
laboratory and multi-
laboratory validation

Laboratory Analysis

ERP Orientation and Other
seminars

Method Development and Implementation

AOAC Consulting Service

Reviewed & Recognized

Official Methods of
Analysis

Proficiency Testing

- *Eurofins*
- *Herbalife*
- *Nature's Way*
- *Nestle*
- *Waters*

Thank You!



In Food & Agriculture, We Set the Standard

CURRENT BIDSİ ACTIVITIES



Determination of Folic Acid in Chewable Gels, Soft Gels and Tablets (Folic-Acid-in-Dietary-Supplements-Proposal-9.16.21.pdf* (aoac.org) - *Call for Methods posted.*

**Standards Workstream supported by Pharmavite*

Voluntary Consensus Standard for the Determination of Pyrrolizidine Alkaloids in Teas, Herbal Infusions, and other Foods Containing Herbal Ingredients (AOAC-Pyrrolizidine-Alkaloids-Proposal-6.11.21.pdf)

Launched on 3-27-2023

SCOPE OF WORK

Community of stakeholders with an interest in developing standards and methods of global relevance for the analysis of 35 PAs in teas, herbal infusions, herbs, seed spices, and botanical dietary supplement ingredients.



ABOUT THE WGPA – JOIN THE WGPA

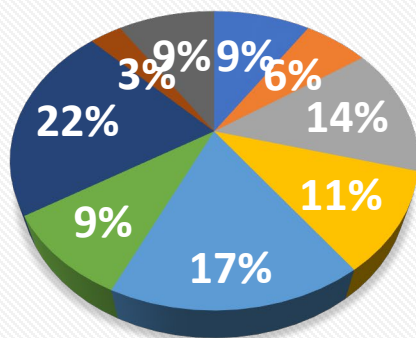


▶ Working Group Co-chairs:

- ▶ Dr. Anja These (Bundesinstitut für Risikobewertung (BfR))
- ▶ Dr. Lukas Vaclavik (Eurofins)

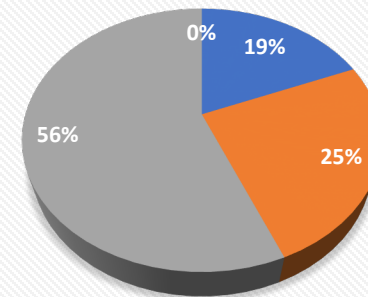
▶ Working Group Members

Expertise



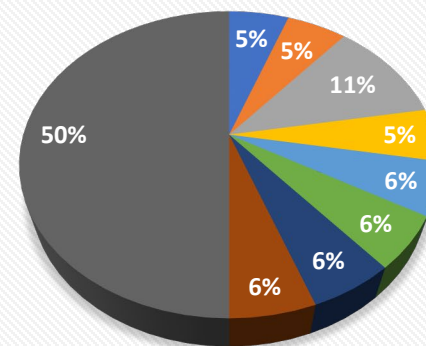
- Analytical Chemistry
- Botanical analysis
- Botanicals & Dietary Supplements
- Contaminants & biotoxin
- Method development
- Natural products
- Pharmakinetiks
- PAs

Broad Sector



- Academia
- Government
- Industry
- NGO

Region



- Canada
- China
- Germany
- India
- Italy
- Morocco
- New Zealand
- Switzerland
- USA

CALLS TO ACTION – COLLABORATING WITH AOAC



Method Review

- AOAC Core Science Programs
 - AOAC *Official Methods of Analysis*
 - AOAC *Reviewed and Recognized*

Subject Matter Expertise

- Developing standards, guidance, methods, etc....
- Weigh in on what is really possible and practical... in the laboratory
- Best practices
- Join one of our programs/working groups through the Call for Experts



Method Development & Submission

- Method development & optimization
- Method Validation
- Method submission of fit for purpose methods
- Fit for purpose methods are needed

Sharing and Collaboration

- Publications
- Discussion forums
- Attend AOAC Annual Meeting
- Join the Community on LinkedIn
- Propose an Emerging Topic, working group or program to AOAC

ENGAGE, NETWORK & STAY IN THE KNOW



137th Annual Meeting • August 25-30, 2023 • New Orleans, LA



ANNUAL MEETING: A UNIQUE ANALYTICAL SCIENCE OPPORTUNITY

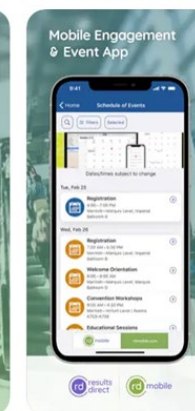
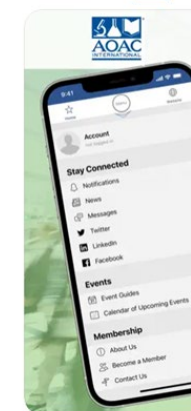
- ▶ **Businesses:** Meet scientific and regulatory experts and engage with new trends and standards.
- ▶ **Scientists:** Build professional expertise and network with your community to share information and best practices.
- ▶ **Regulators:** Leverage unprecedented opportunity for stakeholder collaboration on complex testing and analysis challenges, helping improve compliance and public safety.



AOAC INTERNATIONAL
AOAC INTERNATIONAL
Free



Screenshots [iPhone](#) [iPad](#)



AOAC'S NEW YEAR-ROUND APP

- ▶ AOAC News
- ▶ Events
- ▶ Social Media Links
- ▶ Publications
- ▶ Comprehensive Meeting Information

In Food & Agriculture, We Set the Standard

AOAC WGPA STAFF TEAM RESOURCES



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JOIN THE ADVISORY PANEL FOR AN AOAC INTEGRATED SCIENCE PROGRAM & PROJECT



Emerging Topics

- Novel foods (alternative protein sources)
- Ethylene Oxide
- Mushrooms



INDIVIDUAL WORKING GROUPS

Color Additives from
Natural Sources

Heavy Metals in Foods

PFAS



תודה
Dankie Gracias
Спасибо شكرًا
Merci Takk
Köszönjük Terima kasih
Grazie Dziękujemy Děkojame
Ďakujeme Vielen Dank Paldies
Kiitos Täname teid 谢谢
Thank You Tak
感謝您 Obrigado Teşekkür Ederiz
Σας ευχαριστούμε 감사합니다
Bedankt Děkujeme vám
ありがとうございます
Tack

