In Food & Agriculture, We Set the Standard

BOTANICAL INGREDIENTS & DIETARY SUPPLEMENT INTEGRITY

A multi-year, integrated science program to support the analytical needs of the Botanical and Dietary Supplement Community

OVERVIEW

AOAC INTERNATIONAL (AOAC) is proposing a new multi-year program funded by stakeholders to collaboratively re-invigorate efforts to address current and newly emerging analytical needs within the botanical and dietary supplement community. The AOAC Botanical Ingredients and Dietary Supplement Integrity program (BIDSI) is designed to provide raw agricultural producers, manufacturers, testing laboratories, and retail establishments with the analytical resources necessary to ensure product integrity, including reliable Certificates of Analysis (*i.e.,* quality and accurate labeling for identity, purity, strength, and composition).

To build upon AOAC's compilation of previously published analyte-specific Standard Method Performance Requirements (*SMPRs®*) and fit-for-purpose *Official Methods of Analysis*℠, BIDSI offers a multi-faceted approach that encompasses the following workstreams:

- Development of method performance standards for submission of methods for new components, dosages, environmental contaminants, and novel matrices,
- Species identification (botanicals and probiotics) employing next generation sequencing applications, molecular technologies,
- Updates for validation and verification criteria (AOAC Appendix K)
- Training and education programs

As part of this effort, AOAC is also committing to re-evaluating and updating those "orphaned" SMPRs for which no methods were submitted through our previous program.

BACKGROUND

Dietary supplements are a class of products intended to augment nutritional intake and/or ensure that an individual gets enough of the vital substances the body needs to function. They are not intended to treat, prevent, or cure diseases, used as a conventional food or as a sole item of a meal. Many ingredients in dietary supplements are regarded as nutritionals. Examples include water- and fat-soluble vitamins, co-factors, minerals, herbs, botanicals, and enzymes alone or in combination. By most international standards, they are intended to be taken orally and are marketed in multiple dose forms (*e.g.,* as tablets, capsules, soft gels, gel caps, powders, and liquids) and dosages.

In the United States, botanical and dietary supplement safety and integrity are regulated under The Dietary Supplement Health and Education Act of 1994 (DSHEA) with authority granted to the U.S. Food and Drug Administration under 21 CFR, Part 111 (2007), "*Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements."* 21 CFR, Part 111 (2007) defines the responsibilities industry must take to ensure quality through Good Manufacturing Practices. Key points regarding analytical test methods and validity of results include:

- 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.

In the European Union, the manufacturing and trade of herbs and dietary supplements are regulated by pharmaceutical and food laws. While dietary supplements are subject to food laws, regulatory provisions dealing with herbs are found in pharmaceutical regulations. Regulatory oversight in Asia-Pacific Countries (APAC) *e.g.,* China, India, Australia, Korea, and Southeast Asia (ASEAN) is similarly compartmentalized to varying degrees between food and pharmaceutical regulations.

The 2021 market for botanicals and dietary supplements according to consumer sales was $48.5B in the US and $151.9B globally. The expansion of product offerings has rapidly exploded worldwide. The COVID-19 pandemic, the exponential growth of on-line sales, and trends in CBD-containing product development and market availability are recent contributing factors. The result has been a renewed call for increased regulatory scrutiny, awareness of product integrity and safety, and a greater collaborative environment among stakeholder communities that include growers, manufacturers, retailers, and regulators. Notable industry-led initiatives include the "Tested to be Trusted" Program (CVS, 2019), COA from an ISO/IEC 17025 accredited

laboratory (Amazon, 2020), and the formation of the Global Retailer and Manufacturer Alliance (GRMA) Dietary Supplement Integrity Committee (2022).

AOAC AND DIETARY SUPPLEMENTS

AOAC has been a leader within the dietary supplement analytical community since 2001. Between 2001 and 2013, in collaboration with the National Institutes of Health Office of Dietary Supplements, AOAC adopted 11 official methods of analysis along with training materials, validation guidelines, a section in the AOAC Laboratory Accreditation Criteria Committee guidelines, a dedicated chapter in the AOAC *Official Methods of Analysis*SM and a dedicated section of the Journal of AOAC INTERNATIONAL to the measurement of dietary supplement components. From 2013 to 2018, AOAC INTERNATIONAL, in a continued collaboration with the National Institutes of Health Office of Dietary Supplements, embarked on a large-scale stakeholder program to develop much needed consensus-driven performance standards and analytical methods for ingredients used in dietary supplements. As a result of this five-year effort, 34 Standard Method Performance Requirements (*SMPRs)* were adopted, and 16 methods were approved for First Action Status as *Official Methods of Analysis*SM for 25 high priority ingredients.

In the intervening years since the program's completion, new regulations, new product offerings and expanding consumer markets, have brought greater attention to recognized analytical gaps needed to support dietary supplement quality and safety for producers, retailers, and consumers alike. In addition, large retailers of dietary supplements are moving towards requiring that all such products bear a certificate of analysis (*i.e.,* tested by an accredited laboratory using validated compendial methods).

Botanicals and dietary supplements are specific types of matrices with different types of delivery systems and dosages. As such, performance standards and current *Official Methods of Analysis*SM for such analytes in food matrices may not be suitable (*i.e.,* fit-for-purpose,) to quantify the same analytes in dietary supplement dose forms such as chewable gels, soft gels, and tablets.

MOVING FORWARD WITH AOAC's BIDSI

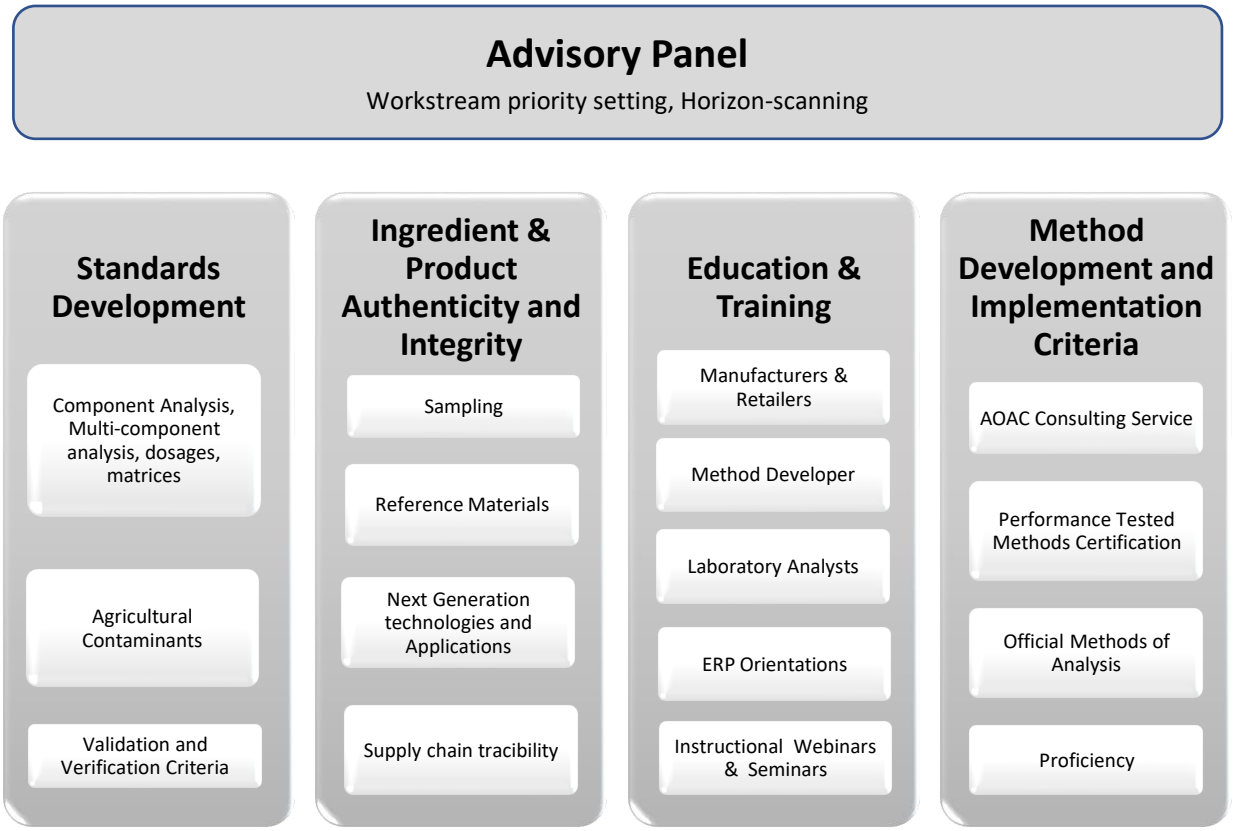
AOAC INTERNATIONAL is seeking financial support to launch the ***Botanical Ingredients and Dietary Supplement Integrity program***. Based on our 20 years of analytical support and accomplishments in this product sector and as a continuing partner with the above-mentioned stakeholder communities, this program will:

- 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.

Based on input received, we have already seeded this new program with two projects designed to address dosage claims and contaminant analysis. These include: Voluntary Consensus Standard for the Determination of Folic Acid in Chewable Gels, Soft Gels and Tablets (Folic-Acid-in-Dietary-Supplements-Proposal-9.16.21.pdf (aoac.org) for which a standard has recently been adopted; and, 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) that is about to get underway.

It is important to note that this program is designed to support parallel workstreams to address multiple but distinct interests. These can be undertaken simultaneously with adequate Advisory Panel support for each workstream. Advisory Panel members will help to steer the overall work of the BIDSI while focusing on workstreams that will address their specific next-generation technology interests/needs.



Seeking Support

BIDSI will be guided by an Advisory Panel comprised of funding organizations from government, industry and academia to confirm priorities and working group objectives. This panel will meet quarterly to review progress and consider additional objectives.

To launch this multi-year effort, AOAC INTERNATIONAL is asking organizations to join this important program with an annual contribution of $10,000. Other levels of contributions will be considered as well[1]. Each individual workstream will require $80,000 to begin working group activities[2].

Funding will support the following for each workstream[3]:

- Identification of and recruitment for working groups and members,
- Facilitating AP meetings, working group and subgroup meetings (when needed) for drafting of consensus documentation,
- Coordination of all program meetings
  - Two (2) annual in-person program meetings,
  - Working group meetings and subgroup meetings (both in-person, web conference, and online collaboration)
- Processes for drafting documents and consensus building,
- Publication of approved consensus documents,
- Travel for no more than three (3) invited key experts needed to complete the work.

Benefits as an Advisory Panel Member

- Multiple workstreams for prospective AP members to select based on your priority analytical needs,
- Leadership in establishing consumer confidence by driving the development of internationally recognized performance standards that will foster the development of *Official Methods of Analysis,*
- Engagement with a select group that will set benchmarks for quality and product integrity,
- Opportunity to drive the development of criteria for novel applications for botanical testing that incorporate cutting edge technologies to ensure botanical authenticity,
- Steer the revision and updating of globally accepted method validation criteria and method verification criteria to ensure proper method implementation,
- Lead the development of needed laboratory end-user guidance and quality testing program components for the botanical and dietary supplement community.
- Earn financial discounts on select AOAC INTERNATIONAL Science Programs
- ***Ensure that all testing data provided in a COA is accurate and reliable which will translate into consumer safety and trust.***

Contact Information

Alica Meiklejohn
Director, Business Development

AOAC INTERNATIONAL
2275 Research Blvd., Suite 300
Rockville, MD 20850
Tel: 301-924-7077; ext. 101
ameiklejohn@aoac.org
www.aoac.org

[1]AOAC INTERNATIONAL will continue to explore a multi-tiered funding schedule to avoid any unintended barrier to the ultimate success of this project and to encourage as many stakeholders to get involved as possible.

[2]Each workstream at $80,000 supports a maximum of two (2) working groups depending on the scope of work.

[3]Costs associated with method submission and review are separate and in addition to the fees for launching any workstream.