

BOTANICAL INGREDIENTS & DIETARY SUPPLEMENT INTEGRITY



Dietary supplements describe a class of food products intended to enhance nutritional intake and/or ensure that an individual gets enough of the vital substances the body needs to function. In 2023, the market for botanicals and dietary supplements, according to consumer sales, was \$53.6B in the US and \$123.9B globally with an estimated compound annual growth of 9.1%.1¹

Botanicals and dietary supplements are regulated differently from country to country. Beyond the regulatory requirements imposed per country, there is also an ongoing effort across the botanical and dietary supplement community to ensure quality, safety and integrity. As a result of heightened consumer awareness and interest, industrial companies and various standards organizations have increased efforts to drive development of consensus standards and fit-for-purpose analytical methods. This drive is especially important as a way to keep up with this innovative and dynamic market with the new types of products, dosages, and forms of delivery.



As a standards developing organization, AOAC INTERNATIONAL has more than 20 years of

experience in providing analytical solutions for the botanical ingredient and dietary supplement sector. To address the new and ongoing analytical challenges in this industry, AOAC developed the Botanical Ingredients and Dietary Supplement Integrity (BIDSI) program, launched in 2023. This program utilizes financial support provided by various organizations which make up the Advisory Panel. The Advisory Panel prioritizes initiatives that instill confidence in test data and address stakeholder needs under the following pillars:

- Standards Development Standard Method Performance Requirements (SMPRs®) for analytical methods such as component analysis, multi-component analysis, specific analytes, matrices, residues and contaminants, as well as Standard Guidance document(s) on the validation and verification for identify testing or other specified areas.
- Ingredient and Product Authenticity and Integrity sampling, reference materials, next generation technologies and applications, and supply chain traceability.
- Education and Training for or by manufacturers and retailers, method developers, laboratory analysts, and instructional webinars and seminars.
- Method Development and Implementation Criteria AOAC Consulting Service, *Performance Tested Methods*SM certification, *Official Methods of Analysis*SM, and Proficiency Testing.

Becoming an Advisory Panel member offers the opportunity to prioritize your needs, drive the development of internationally recognized performance standards, and identify analytical methods that ensure all testing data provided in a Certificate of Analysis (COA) is accurate and reliable, which will translate into consumer safety and trust, and much more.



¹<u>www.grandviewresearch.com</u>; January 27, 2025.

Recent Work of BIDSI

Based on the perspectives of the BIDSI Advisory Panel members and input from other key stakeholders within the dietary supplement community, AOAC hosted a Botanical Identity (BotID) Verification Virtual Forum in January 2024 that attracted over 100 attendees and highlighted the challenges and need for a realistic, statistically relevant guidance document (revised and expanded OMA Appendix K, Parts II and III) on how to verify botanical identity. The BotID Verification initiative was launched in June, and the Working Group is on target to have the Working Group comment period of Part II completed by the end of March 2025, while continuing work on adding examples to Part III.

From the chemical residue and contaminant perspective, AOAC's ethylene oxide project included stakeholders from the food industry as well as BIDSI due to its broader scope of use and impact. The Working Group was launched in January 2024 and the SMPR[®] was published in September of 2024 (AOAC SMPR[®] 2024.005) with the call for methods for ethylene oxide residue analysis ongoing. Also in 2023, the pyrrolizidine alkaloids SMPR[®] was published in November 2023 (AOAC SMPR[®] 2023.002) and two methods are currently under review by the newly seated Expert Review Panel.

In the nutrients arena, a method was reviewed against the Folic Acid SMPR[®]2022.002 and approved and published as AOAC 2024.09 First Action Official Method.

At the AOAC Annual Meeting, in August 2024, presentations at the BIDSI session included topics such as DSHEA and the regulatory landscape of botanicals and dietary supplements, updates on the BotID verification working group, and the use of HPTLC and DNA-based methods in botanical and fungal identity verification.

2025 Program Outlook

During 2025, in addition to completion of the previously launched initiatives, such as the guidance document on botanical identity verification and methods for ethylene oxide residues (ethylene oxide and 2-chloroethanol) and pyrrolizidine alkaloids, a new functional mushrooms initiative is slated to begin.

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