In Food & Agriculture, We Set the Standard

Voluntary Consensus Standard for the Determination of Folic Acid in Chewable Gels, Soft Gels and Tablets

AOAC 2021 Initiative

AOAC INTERNATIONAL is proposing the establishment of a working group to develop a voluntary consensus standard (or standards) for the determination (quantification) of ***folic acid*** in a variety of dose forms, including chewable gels, soft gels, and tablets to address the absence of a validated compendial method suitable and specific to dietary supplement matrices and dosages. The working group will develop one or more Standard Method Performance Requirements, SMPRs® (as deemed necessary by WG experts) based on priorities established by the project's Advisory Panel (see below).

Background

From 2013 to 2018, AOAC INTERNATIONAL in 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*℠ for 25 high priority ingredients.

In the intervening years since the program's completion, product offerings, availability, and usage have expanded exponentially and brought greater attention to recognized analytical gaps needed to support dietary supplement quality and safety for producers and consumers.

Many ingredients in dietary supplements are regarded as nutritionals, *e.g.,* water- and fat-soluble vitamins, co-factors, etc. Though standards and compendial methods do exist for some of these analytes (principally in infant and follow-up formula), it is recognized that their inclusion in dietary supplement formulations pose a unique analytical challenge. Dietary supplements are specific types of matrices with different types of delivery and dosages. As such, performance standards and current *Official Methods of Analysis*℠ may not be suitable *i.e.,* fit-for-purpose, to quantify analytes in products such as chewable gels, soft gels, and tablets.

The need for a re-evaluation of existing SMPRs, new SMPRs and compendial methods is being driven by other factors as well. Large retailers of dietary supplements are moving towards requiring that all such products be tested in accredited laboratories using validated methods, validated methods that may not exist.

To assist the dietary supplement industry, testing laboratories, and retail establishments, AOAC INTERNATIONAL is now proposing to re-invigorate its efforts to address these challenges in a collaborative program to establish new SMPRs and fit-for-purpose *Official Methods of Analysis*[SM] that meet stakeholder needs and provide greater confidence to consumers. As there is currently no standard or compendial method for folic acid, AOAC INTERNATIONAL proposes a project to address this analytical gap as a first step.

Seeking Support

The Folic Acid Advisory Panel will be comprised of funding organizations to determine initial priorities and working group strategies. This panel will meet quarterly to review progress and consider additional objectives based on working group accomplishments and any new challenges that may arise. The projected funding level needed to complete this initiative as described is $80,000 (see Appendix 1 for services provided). We are asking organizations to join this important project for a contribution of $10,000. Other levels of contributions will be considered as well[*].

Benefits for You

The dietary supplement community

- Ensure that project priorities meet your needs through AOAC INTERNATIONAL's unique standard development process,
- Encourage the development of *Official Methods* which provide the highest level of analytical confidence for authenticity claims and detect fraudulent adulteration in priority commodities,
- Provide a validated analytical means needed to meet regional and internationally adopted regulatory requirements,
- Protect producers, retailers, and consumers alike, maintain the reputation of products and ultimately improve the quality and safety of the food supply, and
- Develop capability for meeting the new and emerging testing requirements of large retailers.

Method developers

- Influence the development of consensus standards, which will be used by AOAC Expert Review Panels to evaluate your candidate methods for possible adoption as AOAC *Official Methods of Analysis*,
- AOAC *Official Methods of Analysis*[SM] will be the benchmark for trade resolution, industry testing, to instill consumer confidence, and contribute to consumer safety.

For all

- Create much-needed reference methods for commodities that do not currently exist,
- Generate reliable data for effective compliance-driven quality control of dietary supplement

ingredients and finished products.

[*] *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.*

CONTACT INFORMATION

Palmer A. Orlandi, Jr., Ph. D.
Chief Science Officer/Deputy Executive Director
AOAC INTERNATIONAL
2275 Research Blvd., Suite 300
Rockville, MD 20850
Tel: 301-924-7077; ext. 163
porlandi@aoac.org
www.aoac.org

Alica Meiklejohn
Director, Business Development
AOAC INTERNATIONAL
2275 Research Blvd., Suite 300
Rockville, MD 20850
Tel: 301-924-7077; ext. 101
ameiklejohnrlandi@aoac.org
www.aoac.org

APPENDIX 1

The base fee per Working Group is $80,000 USD and includes:

- ***Advisory Panel Meetings****. AOAC will hold an Advisory Panel Meeting to identify renowned subject matter experts and to identify additional key authorities and experts to participate on AOAC working groups.*
- ***AOAC Stakeholder Meeting****. Working Group Chairs will present the Working Group launch presentation and the stakeholders will refine fitness for purpose.*
- ***AOAC Working Group Meetings****. The Working Groups will hold a series of teleconferences, as needed, to complete the draft SMPR(s).*
- ***AOAC Stakeholder Meeting****. Working Group Chairs will present draft SMPRs for approval by the stakeholders. Stakeholders will deliberate and reach consensus on and thereby approve a final version of the SMPR(s).*
- ***Publication Costs.*** *SMPR(s) approved by the stakeholder community will be published in A*OAC venues (i.e., *Official Methods of Analysis of AOAC INTERNATIONAL* and AOAC Website).
- ***Training and education materials/webinar(s) for method developers.***

Additional Fees:
NOTE: All methods submitted based on any approved SMPR will require the follow:

1. Application Fees for *Official Methods℠* Review - $35,000 USD per method[1]:
   - Includes recruitment of Expert Review Panel (ERP) Members (Volunteer Experts),
   - Includes Preparation and Review of Methods for Review,
   - Includes ERP Orientation and Facilitating ERP Meetings,
     - Initial in-person meeting and, if methods are adopted, maintenance of ERP over the two (2) year method tracking period,
   - Includes ERP review of Method Modifications during the 2-year tracking period,
   - Includes Publications of methods and method manuscripts.

2. Application Fees for Modifying or Extending an Official Method of Analysis - $10,000 per method:
   - Includes Preparation and Review of Methods for Review,
   - Includes ERP Orientation and Facilitating ERP Meetings,
     - Initial in-person meeting and if methods are adopted, maintenance of ERP over the two (2) year method tracking period,
   - Includes ERP review of method during the 2-year tracking period, if required
   - Includes Publications of methods and method manuscripts.

[1] Base application fee. AOAC Organizational Member discounts may apply.

Optional Enhancements (per method):

- Consultation on validation test protocols: $3,000 USD
- Drafting Protocols & Review of Protocol: $3,000 USD
- Drafting of Method in AOAC Format: $2,000 USD
- Drafting of Method Manuscript in AOAC Format: $5,000 USD

NOTE: Travel costs of ERP members and coordination of laboratory work if needed are not covered. New application fees for resubmission will be required if an ERP does not approve the initial method submission.