In Food & Agriculture, We Set the Standard

Voluntary Consensus Standards for Color Additives from Natural Sources

AOAC 2021 Initiative

AOAC INTERNATIONAL is proposing the establishment of one integrated working group composed of four contaminant-specific subgroups to develop and adopt voluntary consensus standards for color additives from natural sources. Stakeholder-approved standards will be used in the development of *Official Methods of Analysis* for microbial contaminants, residual solvents, pesticide residues, and heavy metal contaminants in naturally derived color additives. Each sub-group will develop and adopt one or more Standard Method Performance Requirements, *SMPRs*® based on priorities established by the project's Advisory Panel (see below).

Background

Internationally, with the consumer demand for "natural" colors increasing, some food manufacturers are turning away from synthetic color additives and towards those from plant extracts or other natural sources. Under current US regulation, color additives fall into two categories: those subject to FDA's certification process, which include synthetic color additives and are tested by the FDA, and those that are exempt from certification where it is up to manufacturers to comply with specifications. From a quality and safety perspective, identity and purity specifications for colors from natural sources are not as well defined or monitored as for FDA certified colors which may increase the risk of adulteration. Natural colors also have regulatory requirements for the crops that are producing the colors and are covered under FSMA Preventive Controls and Produce Safety Rules. These regulations require control measures to be in place to ensure the hazards identified in the risk assessments have been addressed. Consistent industry-wide safety standards are needed to address the manufacturing, processing, application, and international trade of colors from natural sources to ensure quality and safety throughout the supply chain. Methods for microbiological contamination, heavy metals, pesticides, and unauthorized solvents are some of the means to establish these standards. This project will provide consensus standards to support method development for overcoming current analytical challenges.

Seeking Support

The Natural Colors Advisory Panel will be comprised of funding organizations to determine initial priorities and define working group strategies within the four areas of concern. These include standards development for methods concerning microbial contaminants, residual solvents, pesticide residues, and heavy metals. 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 needed to complete this project as described is $80,000 (see Appendix 1 for services included). In recognition of the foundational work already established within the AOAC Colors Community, this cost will cover the separate and distinct needs to manage work for each of the four sub-groups. We are asking organizations to join this important project for a contribution of $10,000. Other levels of contributions will be considered as well[1].

Benefits for You

Method developers

- Influence the development of consensus standards in four defined areas of concern for natural colors that will be used by AOAC Expert Review Panels to evaluate candidate methods for possible adoption as AOAC *Official Methods of Analysis*.
- AOAC *Official Methods of Analysis* will be the benchmark for trade resolutions, instill consumer confidence, and contribute to consumer safety.

Food manufacturers or food distributors:

- 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 the foundation necessary to meet regional and internationally adopted regulatory requirements through consensus standards and validated *Official Methods of Analysis*,
- Protect producers and consumers alike, maintain the reputation of products and ultimately improve the quality and safety of the food supply.

For all:

- Create much-needed reference methods for commodities that do not currently exist,
- Generate reliable data for effective compliance-driven quality control of food materials and products.

CONTACT INFORMATION

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APPENDIX 1

The base fee for the proposed Working Group of $80,000 is based on the formation of an integrated working group with activities for four (4) subgroups. This 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 Meetings****. Two meetings will be held to include the following activities:*
  - *Working Group Chairs will present the Working Group launch presentation and the stakeholders will refine fitness for purpose,*
  - *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).*
- ***AOAC Working Group Meetings****. The Working Groups will hold a series of teleconferences, as needed, to complete the draft 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 developer.***

Additional Fees (as applicable):

1. Application Fees for *Official Methods*^{SM} Review - $35,000 USD per method[2]:
   - 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 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 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.

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 to meetings and coordination of laboratory work, if needed are not covered. New application fees for resubmission may be required if an ERP does not approve the initial method submission.

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