



In Food & Agriculture, We Set the Standard

Gluten and Food Allergens Methods Program

The Food Allergens Community has long recognized gaps and impediments that have limited the certification and/or adoption of methods to demonstrate reliable performance and reproducibility. In part, these include reference materials and incurred sampling and usage; validation guidelines to evaluate method performance; training; and, proficiency.

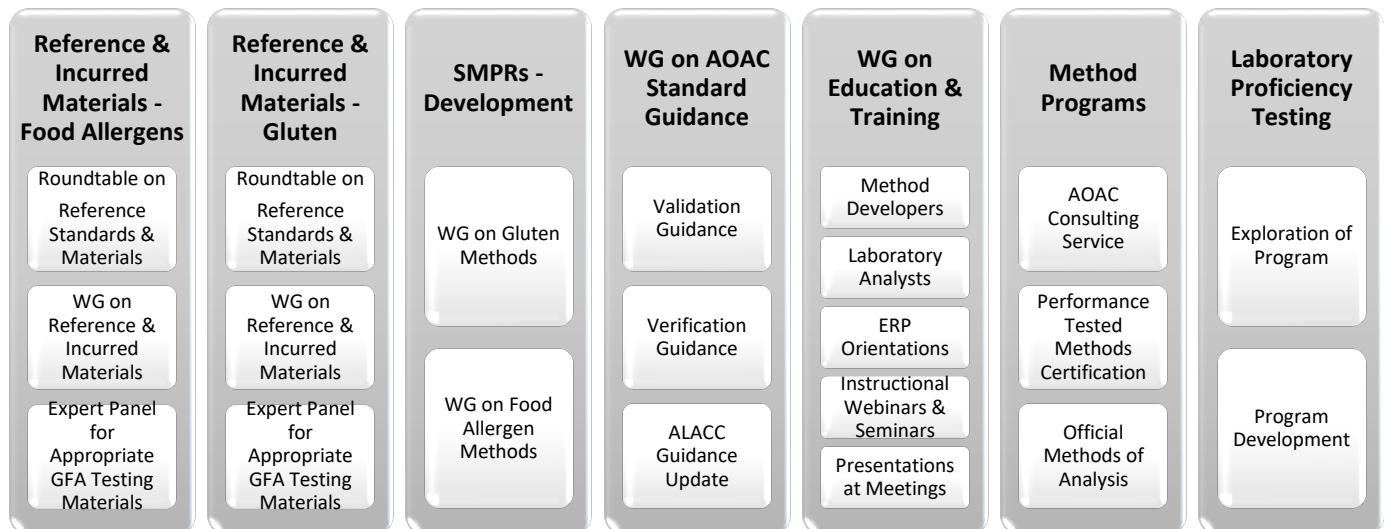
AOAC 2020 Initiative

AOAC INTERNATIONAL is proposing the formation of a funded, multi-year science program for food allergens and gluten to coordinate all future consensus-driven needs development, validation and implementation of methods for the analysis of a wide range of food-associated allergens and gluten.

To accomplish this, AOAC INTERNATIONAL will institute an integrated program that will encompass current and future needs through the establishment of multiple working groups. The objectives of each of the proposed working groups are defined as follows:

1. Consensus on and development of reference materials
2. Consensus on and development of incurred materials for testing
3. Consensus reference methods for characterization of materials
4. Consensus standard method performance requirements
5. Consensus on updated validation guidance
6. Proficiency Testing Program for Food Allergen Assays
7. Education and training for Method Developers and Laboratories

Elements of the Proposed AOAC Integrated Science Program for Gluten and Food Allergens



Rationale:

- *AOAC standards development portfolio can develop consensus standards for what is needed for reference and incurred materials where needed, validation and verification guidance, and method performance requirements.*
- *AOAC method programs and consulting services are available to facilitate the validation and review of methods for certification and approval.*
- *AOAC Laboratory Proficiency Testing Program can facilitate an exploratory effort to consider the development of an AOAC program for gluten and food allergens once methods are approved.*
- *AOAC Education and Training is essential to ensure consistency of interpretation and consensus expectations for methods development, validation and approval, and method verification and implementation.*

Background

Most food recalls are due to either microbial contaminants or the unintended adulteration of foods with known allergens and gluten, i.e., through cross-contamination or mislabeling. AOAC INTERNATIONAL has long recognized the significant impact the latter has had (and continues to have) on the health and safety of food allergic populations. Through its stakeholder consensus working groups and its Food Allergens Community, AOAC INTERNATIONAL continues to address the analytical difficulties that have long impeded the development of sensitive and specific testing methods.

In 2014, AOAC INTERNATIONAL launched a working group to develop performance standards for methods to detect select allergens using mass spectrometry. A second working group was established in 2016 to focus on ligand binding assays to analyze for food allergens. Between both working groups, AOAC has developed the following consensus standard method performance requirements (SMPRs®):

AOAC SMPR 2016.002	Hazelnut, Egg, Peanut, and Milk Allergens (Mass spectrometry)
AOAC SMPR 2017.020	Chicken Egg Allergen (ligand-based technology)
AOAC SMPR 2017.021	Gluten in Oats (ligand-based technology)
AOAC SMPR 2018.003	Milk Allergen (ligand-based technology)
AOAC SMPR 2018.012	Peanut Allergen (ligand-based technology)

Subsequent calls for methods based on these SMPRs, however, resulted in very few validated methods published as Official Methods of Analysis. While there are several methods certified as AOAC Performance Tested MethodsSM, only six (6) Official Methods of Analysis for gluten - to include one pertaining to gluten in oats and one for hazelnut, egg, peanut, and milk allergens (mass spectrometry) have been published. Furthermore, no ligand binding methods for food allergens have been published as Official Methods of Analysis.

Seeking Support

The proposed Gluten and Food Allergens Program will be guided by an Advisory Panel comprised of funding organizations 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 proposes to hold 2 thought leader dialogue sessions and establish 3 working groups in the first year. Costs for these activities and for projected activities in follow-on years are detailed in the Appendix 1.

We are asking organizations to join this important project with a contribution of \$10,000. Other levels of contributions will be considered as well¹. Program activities can commence once financial support has surpassed \$160,000².

Benefits for You

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 will be the benchmark for trade resolutions, instill consumer confidence, and contribute to consumer safety

Food manufacturers or food distributors:

- Ensure that 2020 program priorities meet your needs through AOAC INTERNATIONAL's standards development process
- Encourage the development of *Official Methods* which provide the highest level of analytical confidence.
- Provide a validated analytical means needed to meet regional and international regulatory requirements
- 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
- Support the development of standards leading to Codex Type II methods for dispute resolution in international trade
- Membership on the program Advisory Panel and discounts on method submissions and consulting fees

Notes on the implementation of the Gluten and Food Allergens Program

- ¹Work can commence once funding needs are met to launch two working groups
- ³Funding will support the following activities:
 - Dialogue with Key Thought Leaders, SMEs and Sponsors to assist with program development
 - Identification of and recruitment for working groups and members
 - Facilitation of working group and subgroup meetings for drafting of consensus documentation
 - Coordination of all program meetings
 - At least one (1) annual in-person program meeting,
 - Working group meetings and subgroup meetings (both in-person and web conference)
 - Processes for drafting documents and consensus building
 - Publication of approved consensus documents
 - Discounts for program supporters on AOAC Consulting Services
 - Travel for no more than three (3) invited key stakeholders/experts needed to complete the work

¹AOAC 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.

²This price reflects the cost for supporting 2 thought leader dialogue sessions and 2 of 4 proposed working groups and their associated publication costs. Additional details can be found in Appendix 1.

³Costs not covered include any needed laboratory work, establishment of one or more subsequent Official Methods expert review panels and any candidate method activities. Final costs will be confirmed in a document of understanding between AOAC INTERNATIONAL and all participating organizations.

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APPENDIX 1 - Program Cost Projections

Total Program Cost: \$830,000 for Four (4) Years with totals for each year represent funding requirements.

YEAR 1	SUMMARY: 2 Thought Leader Dialogue Sessions and 3 Working Groups (WG) – includes AP meetings; GFA program community meetings; working group meetings and publications of outcomes and deliverables		
	Joint Gluten & Food Allergens Reference and Testing Materials	\$ 5,000 @ 2 RT	\$ 10,000
	Virtual Meeting (thought leader dialogue sessions)		
	WG on Gluten Reference & Testing Materials*	\$ 70,000 @ 3 WG	\$210,000
	WG on Food Allergen Reference & Testing Materials*		
	WG on GFA Validation & Verification Guidance		
	WG Publications	\$ 5,000 @ 3	\$ 15,000
		TOTAL YEAR 1	\$235,000
YEAR 2	SUMMARY: WG – includes AP meetings; GFA program community meetings; working group meetings and publications of outcomes and deliverables.		
	Joint WG on Gluten & Food Allergen Analysis*	\$ 70,000 @ 4 WG	\$280,000
	WG on GFA Reference & Testing Materials*		
	WG on GFA Education & Training*		
	WG on PT Exploration		
	Method applications for AOAC <i>Performance Tested Methods</i> SM (PTM) program [†]	\$ 15,000 @ 5 apps	\$ 75,000 ¹
	Method applications for AOAC <i>Official Methods</i> SM (OMA) program	\$ 20,000 @ 2	\$ 40,000 ²
	Publications	\$ 5,000 @ 4	\$ 20,000
		TOTAL YEAR 2	\$415,000
YEAR 3	SUMMARY: 2 WG – includes AP meetings; GFA program community meetings; working group meetings and publications of outcomes and deliverables		
	Joint WG on Gluten & Food Allergen Analysis*	\$ 70,000 @ 2 WG	\$140,000
	WG on GFA Validation & Verification Guidance*		
	Application Fees for conformity assessment programs ^{1, 2}		
	GFA Education and Training Courses ³		
	LPTP Launch ⁴		
	Publications	\$ 5,000 @ 2	\$ 10,000
		TOTAL YEAR 3	\$150,000
YEAR 4	SUMMARY: GFA program community meetings, Program Maintenance; communications; and publications of outcomes and deliverables.		
	GFA Program maintenance (meetings, communication, etc.)	\$ 25,000	\$ 25,000
	Projected new WG activities based on Advisor Panel guidance	\$ 70,000 @ X WG	
	Application Fees for conformity assessment programs ^{1, 2}		
	GFA Education and Training Courses ³		
	LPTP ⁴		
	Publications	\$ 5,000	\$ 5,000
		TOTAL YEAR 4	\$ 30,000+
	TOTAL PROGRAM:		<u>\$830,000</u>

*TDLM and/or TDRM engagement

[†]Does not include application fees for subsequent years

¹ Program application fees paid by method developer organizations.

² Program application fees paid by method developer organizations. May be eligible for additional discount if method is PTM certified or if the submitted method is undergoing modification.

³ Training Course or Webinar Registration Fees Apply

⁴ Participant Fees Apply

