



*In Food & Agriculture, We Set the Standard*

## **The Analytical International Methods and Standards Program, AIMS**

AOAC INTERNATIONAL implemented a new strategic operating model in 2018 that transitioned from a traditional stakeholder panel model towards one of focused, self-sustaining programs. By design, each program is composed of projects that integrate 5 general pillars that define all new AOAC programs: traditional standards and methods development, proficiency testing, training and education, guidance and consultation, and horizon-scanning within the context of the program's specified theme.

The most recent addition to AOAC INTERNATIONAL's program portfolio is the Analytical International Methods and Standards (AIMS) Program. The objective of the AIMS is to address emerging issues and opportunities in food microbiology among the international stakeholder community.

### **Background**

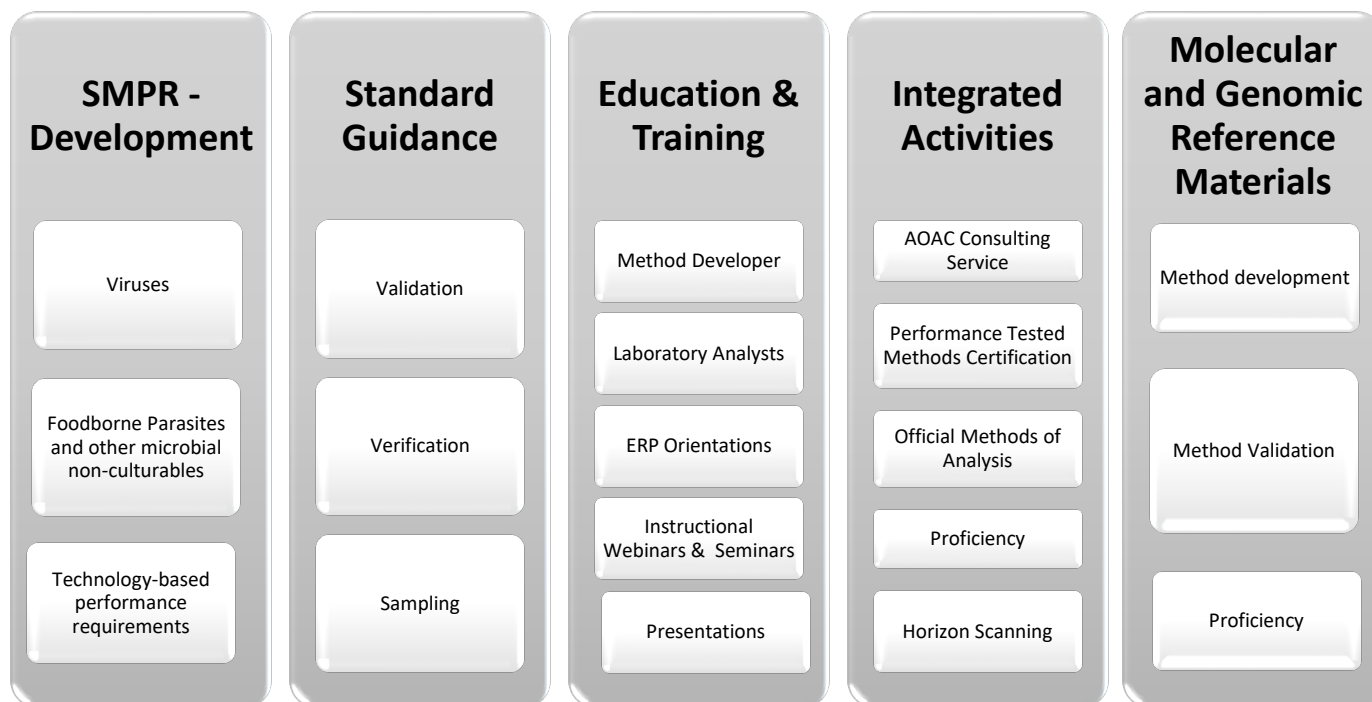
AOAC INTERNATIONAL's International Stakeholder Panel on Alternative Methods (ISPAM) that was established in 2011 to develop harmonized, internationally accepted standard validation guidelines for alternative (rapid) chemical and microbiological methods, and to achieve optimal efficiency and avoid duplication of efforts for the validation of proprietary methods. This broadly defined stakeholder panel consisted of over 200 stakeholders and 6 working groups to focus on specific topics such as microbiological and chemistry validation criteria, fresh produce, allergens, and statistics. ISPAM was officially sunset in 2019.

To maintain a comprehensive scientific portfolio and place greater emphasis on horizon scanning efforts, while ensuring continuity with current microbiological needs, AOAC INTERNATIONAL is now launching the Analytical International Methods and Standards Program, AIMS. It is designed to be a multi-year, self-sustaining umbrella program for projects that will focus on delivering analytical solutions for current capability gaps in laboratory testing, for responding to emerging microbial threats to food safety, and to develop standards for the use of cutting-edge diagnostic technologies and applications.

Such specific areas include – but will not be limited to:

- Alternative method development criteria for emerging microbial contaminants (non-culturable)
- Validation criteria for evaluation of alternative (proprietary) methods
- Novel, recently recognized food, feed, and environmental matrices
- Emergency response procedures to address new and immediate public health threats
- Advanced molecular applications, bioinformatics, and biotechnology opportunities
- Cutting-edge analytical technologies
- Reference method review and harmonization
- Training and educational outreach on all aspects related to the above

## Elements of the Proposed AOAC Integrated Science Program for AIMS



### 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.

## AOAC 2020 Initiative

AOAC INTERNATIONAL is proposing the formation of AIMS as a funded, multi-year science program to be initiated during the 2020 calendar year. AOAC will begin this program with a series of Thought Leader Dialogues<sup>1</sup> through sponsorship with Advisory Panel Members<sup>2</sup> to provide added focus to the strategic objectives of AIMS within the context of the 5 program pillars. Such thought leader topics will revolve around the following proposed projects:

- Development of consensus performance standards for *Official Methods of Analysis* of food-borne viruses, e.g. Hepatitis A virus and Norovirus.
- Development of consensus validation criteria of molecular and genomic methods to include:
  - Extraction and template preparation,

- Platform performance standards,
- Quality control and quality control factors to include:
  - Sequencing coverage,
  - Data integrity,
  - Reference database integrity,
- Guidance on field, manufacturing, and laboratory sampling for testing and obtaining defensible data,
- Updating Appendix J, “AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces,”
  - Developing SMPR for Qualitative Fractional Recovery Metrics,
  - Update Statistical Analysis Appendices,
  - Revise framework for the Appendix,
- Development of an emergency response decision tree and an emergency validation guidance under the auspices of the AOAC RI/PTM Program.

## Seeking Support

AIMS 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 as a result of working group accomplishments.

Advisory Panel members will receive discounts on method submissions and consulting fees.

To launch this multi-year effort, AOAC INTERNATIONAL proposes to hold 2 Thought Leader Dialogue Sessions and establish 2 working groups in the first year.

**We are asking organizations to join this important program with a contribution of \$10,000.** Other levels of contributions will be considered as well<sup>3</sup>. Program activities can commence once financial support has surpassed **\$160,000**<sup>4</sup>.

### Notes on the implementation of the Program<sup>5</sup>

- Funding will support the following initiatives:
  - Roundtable of Key Thought Leaders, SMEs and supporters to assist with program development,
  - Identification and recruitment for working groups and members,
  - Facilitating working group and subgroup meetings (when needed) 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 sponsors on AOAC Consulting Services,
  - Travel for no more than three (3) invited key stakeholders/experts needed to complete the work.

## Benefits for You

### Method developers and laboratories

- 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* are recognized as the benchmark for regulatory applications and international trade resolutions, are used to 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 unique standards development process,
- Encourage the development of *Official Methods* which provide the highest level of analytical confidence in priority commodities
- Provide a validated analytical means needed to meet regional and internationally adopted regulatory requirements,
- Protect producers and consumers alike to 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

## Contact Information

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<sup>1</sup>*Thought Leader Dialogue will involve 1-day sessions between the AOAC INTERNATIONAL Science Team, AIMS Advisory Panel Members, and individual stakeholder groups, e.g. regulatory officials, method developers, research scientists, contract laboratory professionals, etc. to identify needs from their individual perspectives.*

<sup>2</sup>*The AIMS Advisory Panel will be comprised of all financial supporters of AIMS.*

<sup>3</sup>*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.*

<sup>4</sup>*This price reflects the cost for supporting 2 Thought Leader Dialogues (2x \$5,000) and 2 working groups and their associated publication costs (\$75,000/working group).*

<sup>5</sup>*Costs 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 organization.*