



*In Food & Agriculture, We Set the Standard*

# OMA Appendix J Revision Initiative: Updating Guidance for Microbiological Method Validation

## OVERVIEW

AOAC INTERNATIONAL (AOAC) is proposing a new multi-year initiative funded by stakeholders to collaboratively update the Official Methods of Analysis (OMA) Appendix J: AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Microbiological Methods for Foods and Environmental Surfaces. The current version of Appendix J was approved in 2011 and aligned with FDA requirements for validation of methods at the time. Key ISO global validation standard ISO 16140-2:2016 references it. But as microbiological detection, confirmation and identification technologies evolve, the need for revision and updates has become clear.

Building upon the success of the current version of OMA Appendix J, this initiative intends to update and expand this standard guidance to encompass current technologies, regulatory requirements and other testing needs, ensure confidence in results generated by validated methods, and align with ISO and other global standards. Specifically, the following will be addressed:

- Global alignment on matrix categorization, sample sizes and other important aspects
- Alignment on inclusivity/exclusivity requirements
- Considerations for confirmation, identification, and quantitative/semi-quantitative approaches
- Inclusion of parasitic and viral methods
- Statistical model updates

## MOVING FORWARD WITH THIS NEW AOAC INITIATIVE

An initiative of this scope will require multiple working groups focusing on distinct areas, including qualitative, quantitative, confirmation and identification methods, but brought together to build a cohesive and comprehensive approach to microbiological method

validation. Leadership of these working groups will be established under the guidance of an Advisory Panel and in collaboration with the AOAC Microbiology Community and AOAC staff. Each working group will be comprised of a diverse group of experts to bring broad knowledge and perspectives, addressing numerous topics related to different techniques (culture-based, molecular, immunological, mass spectrometric etc.) or other important aspects.

## Seeking Support

The OMA Appendix J Revision Initiative will be guided by an Advisory Panel comprised of funding organizations to confirm priorities and working group objectives. This initiative is partially funded by AOAC Research Institute's Advisory Council, which will have representatives on the Advisory Panel. This panel will meet quarterly to review progress and consider additional objectives.

To launch this multi-year effort, AOAC INTERNATIONAL is asking organizations to join this important initiative with an annual contribution of \$10,000. Other levels of contributions will be considered as well. Funding will support the following for each workstream:

- Project management for convening the Advisory Panel and support of the subsequent technical working groups,
- Oversight of the standard development and consensus building processes,
- Facilitation of global alignment,
- Publication of approved voluntary consensus standard documents,
- External outreach and training events to publicize the work of the group as well as to attract additional scientists.

## Advisory Panel Member Benefits

- Leadership in development of updated and new standard guidance for validation of a broad spectrum of microbiological methods,
- Driving development of state-of-the-art, internationally recognized methods via Performance Tested Methods<sup>SM</sup> and Official Methods of Analysis<sup>TM</sup> programs,
- Ensuring confidence in results generated by the validated methods,
- Supporting alignment with ISO and other global standards,
- Acknowledgment in AOAC's publications and presentations,
- Collaboration on AOAC's webinars and other outreach activities,
- Engagement with other leaders in microbiological testing and method development.

**Contact us at  
scienceprograms@aoac.org or  
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your interest!**

