



MEMORANDUM

DATE: May 2, 2016

TO: Method Developers, AOAC Reviewers/Volunteers for AOAC *Performance Tested Methods*SM and AOAC *Official Methods*SM Programs, and AOAC Technical Consultants and Staff

FROM: Deborah McKenzie, Senior Director - AOAC Research Institute

RE: **TECHNICAL BULLETIN: TB01MAY2016: Guidance and Recommendations of the AOAC ERP for Microbiology Methods for Foods and Environmental Surfaces**

EFFECTIVE DATE: MAY 15, 2016

During the past year, the AOAC Expert Review Panel for Microbiology Methods for Foods and Environmental Surfaces (ERP) has reached consensus on some recommendations that can impact the validation of proprietary and commercial microbiology methods for food commodities and environmental surfaces undergoing review in AOAC *Performance Tested Methods*SM program and/or AOAC *Official Methods*SM program. Coincidentally, these recommendations can also impact the validation protocols in development in the AOAC Consulting Service. These recommendations are on the following pages.

As additional recommendations are made, the bulletin will be updated. If there are any questions or comments regarding the recommendations, please contact me at dmckenzie@aoac.org. Thank you very much.

Decision Date	Effective Date	ERP Decision/Action	Comments
03/16/2016	05/15/2016	<p><u>For Multi-laboratory Studies:</u> If one matrix is chosen for the collaborative study, it should be the largest sample size used in the single laboratory study with the shortest incubation time. The ERP has the discretion for requesting additional matrices, if deemed necessary.</p>	<p><i>The method should be evaluated under the most challenging and stringent conditions.</i></p>
03/16/2016	05/15/2016	<p><u>Number of Replicates for Harmonized Studies:</u> ERP will accept multi-laboratory harmonized AOAC studies conducted using 8 replicates as in the ISO 16140-2 instead of the 12 replicates according to AOAC OMA Appendix J.</p> <p><i>Caveat: In the meantime, McKenzie will ask the AOAC Committee on Statistics to provide information on the power of 12 replicates vs. 8 replicates for the AOAC Annual Meeting. ERP may review again pending information from the Committee.</i></p>	<p>The ERP was asked if it was possible to consider a reduced number of replicates for harmonized AOAC method studies. AOAC OMA Appendix J requires 12 replicates and ISO requires 8 replicates.</p> <p><u>Follow Up:</u> Members of the AOAC Committee on Statistics were consulted and indicated a preference for using 12 replicates.</p> <p>Both FDA and USDA also accept studies done in according to ISO 16140-2 as long as the study includes method comparison with BAM method or MLG method respectively.</p>
03/16/2016	05/15/2016	<p><u>Removal of Candidate Method Confirmation:</u> It is not acceptable to remove the candidate method confirmation in an unpaired collaborative study (transfer of test kit primary enrichment to reference method secondary enrichment and subsequent confirmation) as it is necessary in order to observe for potential false negatives or false positives.</p>	<p>Since the samples are spiked (no issues typically finding the organism) and all PTM and preliminary matrix evaluations were all tested using the extended confirmation. The ERP was asked if it was acceptable to remove the extended confirmation for the collaborative study (transfer of test kit primary enrichment to reference secondary enrichment and subsequent confirmation).</p>

Decision Date	Effective Date	ERP Decision/Action	Comments
03/16/2016	05/15/2016	<p><u>Temperature Claims:</u> If the test kit enrichment is incubated at 41.5°C in the multi-laboratory study (EU temps) and both EU and US incubation temperatures have a +/- 1C range, then it is acceptable to make the claim for 42°C in the US</p>	
03/16/2016	05/15/2016	<p><u>Temperature Claims:</u> In the case of selective agar plates and additional confirmation media in which the temperature requirement for the US is 35± 1°C and for the EU is 37°C, the temperature of 36 ± 2°C can be used and will be acceptable by the AOAC ERP for both reference methods' incubation temperature requirements.</p>	ISPAM approved equivalence of 35 °C and 37 °C for Salmonella primary enrichments.
03/16/2016	05/15/2016	<p><u>Confirmation and Colony Selection:</u> For confirmation, it is acceptable to select only one colony from one agar plate (per enrichment) to follow through to full ID as long as it is confirmed. Since the samples are spiked, it is highly likely that confirmation will be successful with one attempt.</p>	For confirmation, is it acceptable to select one colony from one agar plate (per enrichment) to follow through to full ID? Once again, since the samples are spiked, we are most likely going to find the target organism without more than one attempt.
09/27/2015	05/15/2016	<p><u>Quantitative Statistics:</u> Recommendations for the statistical advisors to come to an agreement on how quantitative microbiological methods are reviewed and to amend the statistical workbooks accordingly</p>	
09/27/2015	05/15/2016	<p><u>Claim for <i>Listeria</i> species:</u> The five (5) new <i>Listeria</i> species should be included in the inclusivity study, wherever available and whenever applicable.</p>	
09/27/2015	05/15/2016	<p><u>Alternative Multi-Laboratory Study Designs:</u> It is acceptable to include up to three (3) collaborators per site using the same equipment as long as all work is performed independently on independent test portions. It is noted that <i>ISO 16140-2</i> allows up to three (3) collaborators in the same location as long as separate sample sets are used and analyzed independently. <i>AOAC OMA Appendix I</i> also allows up to three (3) collaborators in the same location with independent sample sets.</p>	AOAC OMA Appendix D allows a maximum of five (5) collaborators for extreme conditions/equipment (expensive equipment).