AOAC SMPR 2020.XXX; September 9, 2019 Version 2

Standard Method Performance Requirements (SMPRs®) for Quantitative Microbiology Methods for Food and Environmental Samples

1. Purpose:

AOAC SMPRs describe the minimum recommended performance characteristics and acceptance criteria to be used during the evaluation of a method. The evaluation may be an on-site verification, a single-laboratory validation, or a multi-site collaborative study. SMPRs are written and adopted by AOAC as voluntary consensus standards and are used by AOAC in their evaluation of validation study data for method being considered for *Performance Tested Methods*^{SM} or AOAC *Official Methods of Analysis*^{SM} programs. This SMPR may also be used as acceptance criteria for verification at user laboratories. (AOAC OMA, Appendix F, 2019)

2. **Intended Use:**

Laboratory use by trained technicians.

3. Applicability:

Validation or verification of candidate methods used for the quantification or enumeration of microorganisms in foods and environmental samples.

4. Analytical Technique:

Any analytical technique that can meet the performance requirements.

5. Definitions:

a. Candidate Method.—The method submitted for validation that demonstrates or estimates, for a given category of products, the same analyte as is measured using the corresponding reference method. The method can be proprietary or noncommercial and does not need to cover an entire analysis procedure, that is from the preparation of samples to the test report. Also known as the alternative method in ISO validations. The terms “alternative” and “candidate” methods are interchangeable for the purposes of this SMPR. (Microbiology, 2019, 21st Edition); (16140-2:2016, 2016)

b. Reference Method.—Pre-existing recognized analytical method against which the candidate method will be compared. (AOAC OMA, 2019)

c. Quantitative Method.—Method of analysis whose response is the amount (count or mass) of the analyte measured either directly (e.g., enumeration in a mass or a volume), or indirectly (e.g., color absorbance, impedance, etc.) in a specified test portion. (Microbiology, 2019, 21st Edition)

d. Enumeration.—The determination of viable microorganisms in a given test portion. Enumeration can be performed directly or indirectly.

e. Equivalent.—The state or condition of being equal. The methods (candidate and reference) would be considered equivalent within a specified confidence if the acceptance criteria are satisfied.

f. Bias.—measurement bias; estimate of a systematic measurement error, or the systematic difference between the quantitative assigned value and the average of measurement replicate results (16140-1)

g. Confidence Interval.—The estimated range in which an obtained result should enclose the actual concentration. For the purpose of this SMPR, a 95% confidence interval is used.

h. Most Probable Number (MPN).—The maximum likelihood estimate of the contamination in a given matrix using test portions from multiple levels

6. Method Performance Requirements:

Parameters	Performance Requirement/Acceptance Criteria
Candidate Method to Reference Method Equivalence Acceptance Criteria	95% confidence interval of the bias (difference between means) between two methods must fall within -0.5 to 0.5 $\log_{10}$ for a given matrix at a given concentration
Number of Replicates	Method developers may increase the number of replicates tested to improve the confidence of the bias
Comparison of methods with two different principles (e.g., MPN/ threshold methods versus direct enumeration)	When the principal of the two methods are different, the acceptance criteria may be modified prior to the study design. Modified acceptance criteria should be reviewed and approved prior to submission of data

7. System Suitability and/or Analytical Quality Controls:

a. Target and non-target organism controls shall be embedded in the validation or verification study as appropriate.
b. Inhibition controls should be used for method verification for each new matrix as appropriate.
c. Manufacturer must provide written justification if controls are not appropriate to an assay.

8. Validation Guidance:

a. Validation studies should be conducted in accordance with procedures as outlined in Appendix J, **Official Methods of Analysis of AOAC INTERNATIONAL**: *AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces* (2012) or
b. ISO 16140-2:2016: Microbiology of the food chain—Method validation—Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method
Methods validated according to ISO 16140-2 or in a harmonized AOAC/ISO study, must be statistically analyzed according to Appendix J and meet the performance requirements as identified in this SMPR.
c. Collaborative studies and Inclusivity/Exclusivity (excluding total enumeration methods) are required for candidate methods submitted for First Action *Official Methods*^{SM} review and consideration.
d. Method Robustness, Stability, Product Consistency and Inclusivity/Exclusivity (excluding total enumeration methods) Studies are required for *Performance Tested Methods*^{SM} submission.

9. Reference Methods

a. The selection of the appropriate reference method will be determined based on the target analyte and matrix being validated. Examples of acceptable reference methods but not limited to are:
    i. AOAC Official Methods of Analysis
    ii. ISO standards
    iii. US FDA Bacteriological Analytical Manual (BAM)
    iv. USDA FSIS Microbiology Laboratory Guidebook (MLG)
    v. Standard Method for the Examination of Dairy Products (SMEDP)
    vi. Compendium of Microbiological Methods for the Examination of Foods (CMMEF)

10. Maximum Time-to-Result:

None mandated.

11. References Cited:

a. Appendix F, **Official Methods of Analysis of AOAC INTERNATIONAL**: *AOAC INTERNATIONAL Guidelines for the Development of Standard Method Performance Requirements* (2016).

b. Appendix J, **Official Methods of Analysis of AOAC INTERNATIONAL**: *AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces* (2012).

c. Appendix I, **Official Methods of Analysis of AOAC International:** *AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Biological Threat Agent Methods and/or Procedures* (2012).

d. ISO 16140-2:2016 *Microbiology of the food chain—Method validation—Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method*

e. ISO 16140-1:2016 *Microbiology of the food chain—Method validation—Part 1: Vocabulary*