



Date: October 14, 2021

From: Scott Coates, AOAC Research Institute Senior Director

Re: Policy on Dilution Ratio and Test Portion Sizes

The AOAC Research Institute has been requested to provide guidance on the evaluation of test portion sizes smaller than those claimed in the validation.

The Expert Review Panel (ERP) for Microbiology Methods for Food & Environmental Surfaces recently approved the following language in a harmonized approach with the MicroVal Technical Committee. The language is currently under review by the AOAC Official Methods Board (OMB) for approval:

- *If there is any change in the dilution ratio, the changes must be validated.*
Note* Methods cannot claim a different test portion to enrichment broth ratio of a given matrix than that of the ratio of the approved validation. Any such changes must be validated. A smaller test portion of the same matrix may be claimed if the portion to broth ratio is the same as the larger portion that was validated.
- *If a method has an approved validation for a certain test portion size, then the claim for that method may include portions up to that test portion size. To claim a test portion size larger than the approved validated test portion size, then validation is required.*
- *AOAC reserves the right to require validation data to support any deviation in test portion size that is not equal to the test portion size in the approved validation. The smallest acceptable test portion size claimed must be greater than or equal to the smallest portion of the reference method used as part of the approved validation study.*

The proposed guidance provided in this memo are merely statements of our current understanding, and are not AOAC INTERNATIONAL or Research Institute policy. You may use these summaries at your own risk.

Please contact me if you have any additional questions or concerns.

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