



International Association of Food Protection 2019 – Regulatory Updates on the Accepted Use of Rapid Microbial Methods

Hygiena's BAX® System assays have been validated for testing ingredients, finished products, and environmental surfaces both internally and by independent organizations such as AOAC and AFNOR to meet the testing requirements necessary for food producers, regulatory agencies, and third-party laboratories. In order to follow the methods approved by AOAC or AFNOR, the validated enrichment protocols described in the BAX® System User Guide and the kit instructions must be followed.

To further clarify the February 2019 changes in the USDA FSIS Microbiology Laboratory Guidebook (MLG), Hygiena is providing additional information shared by USDA-FSIS senior officials at the International Association of Food Protection (IAFP) annual meeting that was held July 21-24, 2019. The statements and responses below were pulled directly from the presentations provided during the meeting, which are now publicly available to participants.

For specific approvals and/or certifications pertaining matrices and applications, please contact your Hygiena representative for more information.

Dr. William Shaw, USDA-FSIS; Tuesday, July 23, 2019 at IAFP 2019 Annual meeting in Louisville Kentucky; Presentation Entitled "Evaluation of Commercial Molecular Screening Platforms for the Detection of Foodborne Bacterial Pathogens by Food Safety and Inspection Service Field Service Laboratories"

"Detection of inoculated pathogens by each screening technology was comparable to the methods currently in use by FSIS laboratories. Each evaluated technology performed as claimed, and results were acceptable based upon FSIS validation criteria. All evaluated technologies met the performance expectations and were able to detect inoculated pathogens accurately during screening."

Dr. Jose Emilio Esteban, USDA-FSIS; Tuesday, July 23, 2019 at IAFP 2019 Annual meeting in Louisville Kentucky; Presentation Entitled "USDA FSIS Process to Accept the Use of Rapid Microbial Methods"

Are rapid methods allowed for official testing?

"Yes, FSIS does not require or expect any particular method; however, we do expect the user to have documentation that the method has been validated by a recognized international standard organization, such as AOAC, AFNOR, MicroVal, etc. and that the method was verified by the laboratory applying the method."

FSIS has published a guideline for validation of screening methods. FSIS publishes in the MLG the method the Agency is currently using. The user has to provide evidence that the validated method they are using is being used as validated and that it is fit for the intended purpose."

Do you accept AOAC OMA or methods validated via the ISO 16150-2 Protocol?

"Yes, we must have documentation that the validated method has been verified to be fit-for-purpose as it is actively being used. Documentation has to meet the requirements put forth in the FSIS published guideline."

“Verification documentation is necessary to demonstrate that a validated method is performing as expected in the environment in which it is used.”

Does FSIS only accept these validated methods for product exported to the US?

“FSIS does not require or expect a specific method to be used. FSIS auditors evaluated the foreign inspection system, including lab methods used in the official sampling programs. Once product is received at US port-of-entry, FSIS may collect samples that will be analyzed using the official published FSIS method. “

Are there additional requirements that must be met before use?

“FSIS makes available a list of test kits or methods that have been validated for detection of relevant food-borne pathogens (i.e. Salmonella, Campylobacter, Listeria spp. including L. monocytogenes, E. coli O157:H7 and non-O157 STEC). The list is intended to be informational and is not an endorsement or approval of any specific test kit or method, regardless of its inclusion in the list.

FSIS also makes available guidance for test kit manufacturers on the characteristics that are required to be considered when documenting performance.

All 4 platforms (BAX, MDS, BioRad and Gene-Up) were equivalent. We choose the ones that were best fit for our business model.”

Dr. Marcos X. Sanchez-Plata, Associate Professor, Global Food Security, International Center for Food Industry Excellence at Texas Tech University, July 23, 2019. Personal communication on issues related to rapid methods and accepted methodologies for USDA-FSIS.

The recent revision of the MLG describes alternative methodologies to detect pathogens by the use of rapid methods, does this mean that other rapid methods are no longer acceptable?

“No. Periodically USDA-FSIS revises their Microbiological Laboratory Guidebook according to specific needs of their laboratories, including logistic factors. As indicated in several documents published by FSIS, methodologies that have been validated and accepted by AOAC, AFNOR, among others are still acceptable as recognized rapid methods for pathogen detection by FSIS. Any statements indicating changes in the accepted methods are misguided and may create confusion. FSIS does not sponsor or promote a particular method, as long as the methodologies have been validated and recognized by international standard agencies, and that the method has been verified to perform in the laboratories using it. This will include the BAX system as a recognized methodology for rapid detection of pathogens.”

[FSIS Foodborne Pathogen Test Kits Validated by Independent Organizations](#)

[FSIS Guidance for Evaluating Test Kit Performance](#)