

ISPAM Micro Working Group
June 30, 2011
10:30am – 3:30pm
Draft Minutes

Russ Flowers, Silliker, AOAC President
Jim Agin, Q Labs
Patrice Arbault, Bioadvantage Consulting
Marcia Armstrong, Qiagen
Stan Bailey, bioMerieux
DeAnn Benesh, 3M
Reginald Bennet, FDA
Peter Bodnaruk, Ecolab
Yan Cao, Life Technologies
Yi Chen, U.S. FDA CFSAN
Benjamin Diep, Nestle
Peter Evans, USDA FSIS
Phil Feldsine, BioControl
Peter Feng, U.S. FDA CFSAN
Nuri Gras, Labser, Ltda.
Qian Graves, U.S. FDA CFSAN
Brad Goskowicz, Microbiologics, Inc.
Bob Jechorek, 3M
Ron Johnson, bioMerieux
Tom Hammack, U.S. FDA CFSAN
Melinda Haymen, FSNS
Robert LaBudde, Least Cost Formulation
Roxane Lafortune, bioMerieux Canada
Wendy Lauer, Bio-Rad
Zhiyong Li, Guangdong Entry-Exit Inspection and Quarantine Bureau
Tony Lupo, Neogen
Harry Marks, USDA FSIS
Kirsten Mattison, Health Canada
Sam Mohajer, CFIA
Dan Morse, 3M Infection Prevention
Julie Moulin, Nestle
Mark Mozola, Neogen
Palmer Orlandi, U.S. FDA FERN
Wendy Ortman, Decagon Devices
Linda Peng, DuPont
Yvonne Salfinger, Florida State Department Agriculture
Sharon Shea, APHL
Appavu Kalyana Sundaram, Engineering Services, Inc.
Dan Tholen, Dan Tholen Statistical Consulting
Morgan Wallace, DuPont
Pamela Wigler, Cargill

AOAC Staff:
Arlene Fox
Krystyna McIver
Zerlinde Johnson

Working Group Chair Russ Flowers welcomed attendees and indicated that there will be no voting in this meeting, just discussions and consensus on the direction from this ISPAM Micro Working Group as to how to attain the goal of harmonizing the various microbiological guidelines.

A small sub-group of the Microbiology Working Group, key representatives from regulatory agencies and standard setting bodies who developed microbiological method validation guidelines, has been tasked to work on the five top priority areas of divergence and propose a harmonized plan. Sub-group Chair, Phil Feldsine, indicated that the group reached consensus on two of the areas and needed more time to present their harmonization plan to the entire group.

The top five priority areas as decided in teleconference meetings and confirmed at this WG meeting are as follows:

1. Reference Methods
2. Selection of Food/Category (sample matrix)
3. Number of Levels/Samples/Fractional Positive
4. Results analysis & Criteria/Statistical Analysis
5. Number of Samples/Replicates/Method Comparison & Collaborative

More representation from AFNOR and ISO was requested by working group members. Chair Russ Flowers indicated that European representatives, Paul In't Veld and Bertrand Lombard, two key ISO representatives who are currently working on ISO 16140 guidelines, will attend the ISPAM meeting at the AOAC Annual Meeting in New Orleans, LA, but acknowledged that more ISO representation is needed at the working group level.

Regulatory agency representatives were asked to provide their thoughts on the harmonization efforts and those issues of importance to their agencies.

U.S. FDA CFSAN comments were provided by Thomas Hammack:

FDA is interested in the harmonization effort as it impacts international trade and is participating in the discussions to try and harmonize the top priority issues. Of the top five areas of divergence, they are most interested in the use of reference methods and fractional positives. FDA would like to see comparison data on the reference methods with fractional positives in order to consider accepting reference methods other than BAM. It was suggested that proficiency testing data might serve as a tool for comparison of reference method performance. The matrices of particular interest to the FDA include shrimp, leafy green produce, sprouts, and spices.

USDA/FSIS comments were provided by Peter Evans:

USDA/FSIS uses methods in the Microbiology Laboratory Guidelines (MLG). FSIS does not endorse or approve methods for industry. Industry may use a variety of methods to verify the effectiveness of a HACCP plan. FSIS finds AOAC, ISO, and AFNOR methods acceptable for this purpose. USDA/FSIS has the greatest concern for methods that produce false negatives. They would like validation studies to prove that alternative methods do not provide false negative results when compared to the reference method. The USDA FSIS utilizes a one-sided chi square test to analyze unpaired data sets. USDA FSIS performs more replicates to increase the odds of detecting a method that does not perform adequately. USDA FSIS also would like to see a

standard matrix and common strains found in outbreaks used in validations to test the efficacy of the test method to detect these strains. The impact on the assay of larger sample size is particularly of concern to FSIS during validation.

Health Canada (HC) comments were provided by Kirsten Mattison:

Health Canada has been in transition during the revision of the HC guidelines for alternate method validation. Now that the new guidelines are available, it is important to engage the industry and try to harmonize validation schemes for the alternative methods. Harmonization of validation efforts would reduce the time it takes HC to review method submissions. Prevention of false negatives is of greatest concern. Detection of *Listeria* has been the focus of analysis following an outbreak. A main concern of HC is the use of reference methods; ideally HC would like Health Protection Branch (HPB) to be used, or equivalent. Equivalency is decided on a case by case basis. Showing reference methods are equivalent is becoming increasingly important to HC since many alternative methods are not validated in comparison to a HC HPB reference method. Validation of HPB methods must include a minimum of eight government laboratories.

The next steps for the ISPAM Working Group will be for the sub-working group to come to consensus on the five areas of major divergence and provide a proposal for review to the working group to discuss and provide comments. This would ideally happen before the AOAC Annual Meeting. A stakeholder meeting of the ISPAM group will take place on September 16, 2011 in conjunction with the AOAC Annual Meeting in New Orleans, LA, and it is anticipated that the group would vote on the proposals to move forward in the five areas of divergence.