

ISPAM
Working Group on Statistics Meeting
June 29, 2011

Committee on Statistics Attendees:

Paul Wehling, Chair, General Mills/Medallion Labs
Joshua Hicks, Bruker-BioSpin
Robert LaBudde, Least Cost Formulations Ltd.
Roy MacArthur, Food Environmental Research Institute
Julie Moulin, Nestlé S.A.
Dan Tholen, Statistical Consultant
Caryn Thompson, Elanco Animal Health

Observers:

Jim Agin, Q Laboratories, AOAC OMB Member
Stan Bacler, Health Canada, AOAC President-Elect
DeAnn Benesh, 3M Food Safety
Yi Chen, FDA, AOAC General Referee for AOAC Committee on Microbiology
Yan Cao, Life Technologies
Ron Johnson, bioMerieux, Member of AOAC Board of Directors
Peter Feng, FDA
Bob Jechorek, 3M Food Safety
Prabakar Katsuri, PepsiCo
Wendy Lauer, Bio-Rad Laboratories
Markus Lipp, USP
Tony Lupo, Neogen
Jeff Moore, USP
Dan Morse, 3M
Mark Mozola, Neogen
Linda Peng, DuPont Qualicon
Yvonne Salfinger, Florida State Dept Agriculture, Chair of AOAC Committee on Microbiology
Lindell Ward, Covance Laboratories
Morgan Wallace, DuPont Qualicon
Pamela Wilger, Cargill

AOAC Staff:

Arlene Fox
Zerlinde Johnson

Overall goal of the harmonization meeting is to have draft validation guidelines for microbiological and chemical qualitative methods by AOAC Annual Meeting. End goal of this meeting would be a plan on how to help the working groups get the guidance together by September. Assigning of statisticians to the other two working groups to provide input on statistical design for microbiological and chemical qualitative methods.

Statistician Assignments are as follows:

Microbiology WG:

Robert LaBudde
Julie Moulin
Dan Tholen
Paul Wehling

Chemistry WG:

Joshua Hicks
Caryn Thompson
Roy MacArthur
Paul Wehling

It was noted that Max Fienberg is a member of the AOAC Committee on Statistics and will also be involved in this effort. Statistical input from Health Canada and Canadian Food Inspection Agency is welcomed.

The primary responsibilities for this group will be to come to consensus on the parameters and estimators for parameters with advice from the microbiology & chemistry working groups. The working groups will decide on size of study with advice from statisticians. This division of responsibility will help the process and ensure consensus on studies.

Even though there are issues specific to microbiological methods we would like same statistical models for microbiological and chemical qualitative methods.

ISO TC 68 revising standard 5725 standard dealing with quantitative chemical methods
ISO/IUPAC/AOAC – addition of qualitative binary methods. This standard will move forward soon.

Qualitative also called binary methods provide a yes/no; +/-; 0/1, presence/absence result, but method could have thresholds with yes/no output at each threshold.

Dan Tholen spoke about several validation study conditions and parameters that require statistical procedures for analyzing data (Appendix 1).

**Appendix 1: Validation study conditions and parameters that require statistical procedures
(Microbiological and chemical methods)
List by Dan Tholen**

1. Reference method exists.
2. No reference method exists.
3. Reference method exists, but not in the range of interest.
4. Single lab study.
5. Mult-lab study (reproducibility).
6. Chemistry – binary signal (qualitative methods).
7. Chemistry – quantitative signal with threshold.
8. Can quantify concentration.
9. Can not quantify concentration.
10. Can confirm.
11. Can not confirm.
12. Paired with common enrichment or extraction procedures.
13. Unpaired without common enrichment.
14. Unpaired with independent samples (not allowed).

Parameters:

1. LOD
2. Accuracy (trueness and precision)
3. Compare with reference method
4. Agreement among labs