



The Scientific Association Dedicated to Analytical Excellence®

International Stakeholder Panel on Alternative Methods *Meetings of the Working Groups*

Joint Session - Thursday, June 30, 2011 at 8:30am – 10:30am
Concurrent Sessions - Thursday, June 30, 2011 at 10:45am – 3:15pm

PLAZA I & II and Jefferson
HILTON WASHINGTON D.C./ROCKVILLE EXECUTIVE MEETING CENTER

DRAFT AGENDA FOR THE ISPAM WORKING GROUPS

ISPAM JOINT SESSION OF THE WORKING GROUPS (Plaza I & II) (8:30 am – 10:30am)

I. Welcome and Introductions

Dr. Russ Flowers of Mérieux NutriSciences and chair of the working group and the International Stakeholder Panel on Alternative Methods (ISPAM) will greet members and stakeholders and lead introductions. He will also discuss the development of ISPAM and its objectives and goals.

II. Joint Meeting of the Working Groups (Plaza I & II)

Members of the WG on Statistics will elaborate on and discuss statistical models, the differences and similarities between them for the Working Group on Qualitative Chemistry Guidelines and the Working Group on Microbiological Guidelines

- a. **Chi Square and the McNemar Models** – *Dan Tholen, Consultant, and ILAC Liaison to ISO TC69*
- b. **POD** - *Paul Wehling, General Mills*
- c. **LOD, and RLOD Models** – *Robert LaBudde, Least Cost Formulation and Old Dominion University*
- d. **Discussion on specific needs of Working Groups for Qualitative Chemistry & Microbiology** –*Paul Wehling, General Mills*

BREAK 10:30am-10:45am

ISPAM WORKING GROUP ON QUALITATIVE CHEMISTRY METHOD GUIDELINES (Plaza I & II)

(10:45 am – 3:15pm)

III. Working Group Overview

Bert Pöpping, Eurofins and WG Chair will provide an overview of the working group activities and discuss the objectives of this working group meeting.

IV. Review of Current Qualitative Chemistry Method Validation Guidance Documents

- a. Draft AOAC Single Laboratory Validation of the Identification of [botanical or specific botanical material] – *Jim Harnly, USDA - ARS BHNRC*
- b. Draft "Protocol for the Validation of Qualitative methods of Detection." (Joint IUPAC/MoniQA protocol for validation of qualitative methods), Monitoring and Quality Assurance (MoniQA), 2011 MoniQA – *Roy MacArthur, Food & Environmental Research Agency, UK*
- c. "Validation Scheme for Qualitative Analytical Method," ISO Technical Committee 34, Standing Committee 16, Horizontal methods for molecular biomarker analysis, 2011, and "Probability of Detection (POD) as a Statistical Model for the Validation of Qualitative Methods, JAOAC (95) 335 – *Paul Wehling, General Mills*
- d. Draft Standard Format and Guidance for AOAC Standard Method Performance Requirement (SMPR) Documents – *Scott Coates, Chief Scientific Officer, AOAC*
- e. AOAC INTERNATIONAL Guidelines for Validation of Biological Threat Agent Methods and/or Procedures, JAOAC, (94) – *Scott Coates, Chief Scientific Officer, AOAC*
- f. Guide in Validation of Alternative Proprietary Chemical Methods, NordVal Protocol No. 2, Approved 26 May 2010 – *Deborah McKenzie, Sr. Director, AOAC Methods Development and Approval Processes*

LUNCH 12:00pm-12:30pm

V. Comparison of Current Qualitative Chemistry Method Validation Guidance

Scott Coates will provide a summary of the documents outlining and comparing comparison similarities and differences of each document.

VI. Definition of Qualitative Chemistry Methods

Popping will lead the group in a discussion on the definition of qualitative chemistry methods. The objective of the discussion will be to arrive at a recommendation for a definition that will further refine the scope of the working group.

VII. Working Group Philosophical Direction

Popping will lead the working group in discussion on the direction of the working group.

VIII. Next Steps

ISPAM WORKING GROUP ON MICROBIOLOGICAL METHODS GUIDELINES (Jefferson Room)
(10:45 am – 3:15 pm)

I. Working Group Overview

Dr. Russ Flowers of Mérieux NutriSciences and chair of the working group will provide an overview of the working group activities and discuss the objectives of this working group meeting.

II. Summary of Document Comparisons

The working group identified five top priority areas for harmonization. Each will be presented, discussed, and recommendations made to reach harmonization. Microbiological Guidelines that will be compared include FDA, USDA, AOAC, ISO 16140-2, Health Canada, and NordVal.

Reference Top 5 Priority section of ISPAM booklet:

- a. Reference Methods
- b. Selection of Food/Category (sample matrix)
- c. Number of Levels/Samples/Fractional Positive
- d. Results analysis & Criteria/Statistical Analysis
- e. Number of Samples/Replicates/Method Comparison & Collaborative

LUNCH 12:00pm-1:00pm

III. Next Steps