

**Microbiological Working Group Teleconference ISPAM**  
**5<sup>th</sup> floor Conference Room**  
**April 27, 2011**  
**10:30 am – 11:30 am**

**Attendees:**

Russell Flowers – President & ISPAM Chair  
Jim Agin - Q Laboratories  
Stephanie -Campbell Nestle Research Ctr.  
Yan Cao -Life Technologies  
Victor Cook –USDA, FSIS  
Phil Feldsine –BioControl Systems  
Qian Graves -FDA  
Thomas Hammack –FDA,CFSAN  
Ron Johnson -BioMérieux

Magdalena Michulec –Nestle Research Ctr.  
Yvonne Salfinger –Chair, Committee H  
Caryn Thompson –Elanco Animal Health  
Dan Tholen -Statistical Consultant  
Morgan Wallace –DuPont Qualicon  
Paul Wehling –General Mills  
Irene Iugovaz – Health Canada  
Netty Zegers –NEN MicroVal  
Bertrand Lombard -ANSES

**AOAC Staff:**

Scott Coates  
Krystyna McIver  
Deborah McKenzie

Arlene Fox  
Nora Marshall

**Observer:**

Darryl Sullivan -Covance

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- 1 Introduction to AOAC harmonization validation:**
    - a. President Flowers made introduction to Working Group regarding purpose of teleconference and the task of the Microbiological Working Group.
  
  - 2 Determine scope of harmonization:**
    - a. The group agreed that there is a need for a common validation scheme between national and international organizations including mutual recognition of validations.
  
  - 3 Strategy for objective:**
    - a. It was agreed unanimously that available validation schemes be collected:
      - i. ISO 16140 committee draft
      - ii. AOAC Microbiological Guidelines
      - iii. AOAC Microbiological Guidelines Revision Draft
      - iv. MicroVal (utilizes components of ISO & AOAC Guidance)

- v. AFNOR
- vi. Health Canada Compendium Part IV (Qualitative validation)
- vii. NestVal

- b. Develop a flow diagram illustrating the differences between schemes. Defining the requirements of each. (Comparison table)
- c. Drafting a new document signifying the required elements of a validation.
  - i. Primary discussions regarding general technical details essential for validation
  - ii. Secondary discussions regarding supplementary considerations and if these will be contained as part of the validation study or as additional details for the complete package

**4 Sub-Working Groups for strategy objectives:**

- a. President Flowers volunteered to prepare the comparison table outlining the differences and requirements of available validation schemes
- b. The development of a new validation guideline will be prepared by:
  - i. Phil Feldsine
  - ii. Russell Flowers
  - iii. Bertrand Lombard
  - iv. Stephanie Campbell
  - v. Peter Evans
  - vi. Victor Cook
  - vii. Tom Hammack
  - viii. Jim Agin
  - ix. Paul In't Veld

**5 Microbiological Working Group Review of Sub-Groups results:**

- a. The working group will compose observations from the sub-groups results. Thus determining:
  - i. Differences among organizations
  - ii. Common ground for harmonization of validation schemes
  - iii. Comparison of technical requirements
  - iv. Define general needs for single validation. Method performance will be conducted as a separate issue.

**6 Future Teleconferences:**

- a. **May 6<sup>th</sup> 10:30 am** : First Sub-Working Group call to assign members validation schemes and review guideline comparison table.
- b. **May 12<sup>th</sup> 10:30 am**: Full Microbiological Working Group call to present the sub-working groups results.

**7 Adjournment 11: 26 am.**

ACTION ITEMS:

1. Notification to ISO Secretariat requesting an extension to the comment deadline. TBD as to whom will be accepted sender.
2. President Flowers will forward the draft ISO 16140 to Victor Cook - USDA,FSIS.
3. Working Group will forward outlines from NestVal, current MicroVal and ISO 16140 to Krystyna McIver and Nora Marshall.
4. **Krystyna –**
  - a. Forward current list of Microbiological Working Group participants to members for review and suggestions for additional participants.
  - b. Send list of Stakeholder Panel members for review by Working Group for suggestions for additional participants.
  - c. Send Phil Feldsine existing comparison table of AOAC Micro Guideline and ISO.
5. **Nora-**
  - a. Initiate Google Docs account for future document availability.