

Advisory Panel for Harmonization
Establishment of Stakeholder Panel on Alternative Methodology SPAM
AOAC Headquarters
March 15, 2011
8:30 am – 2:15 pm

Advisory Panel:

Russ Flowers	Chairman / Silliker
Phil Feldsine	BioControl
Bob Koeritzer	3M
Yan Cao	Life Technologies
Patricia Meinhardt	R-Biopharm
Linda Peng	DuPont Qualicon
Morgan Wallace	DuPont Qualicon
Keith Jolliff	Qiagen
Ron Johnson	bioMerieux
Todd Ritter	Idaho Technology
Marcia Armstrong	Qiagen

AOAC:

Mark Coleman	AOAC BOD/ Elanco
E. Jim Bradford	AOAC CEO
Krystyna McIver	AOAC Staff
Deborah McKenzie	AOAC Staff
Zerlinde Johnson	AOAC RI Staff
Nora Marshall	AOAC RI Staff
Anita Mishra	AOAC Staff
Alicia Meiklejohn	AOAC Staff
Dawn Frazier	AOAC Staff
Arlene Fox	AOAC Staff

I. Welcome and Introductions – Russ Flowers, Chairman

The term “Proprietary” in the title of the meeting was eliminated due to its exclusivity and replaced with the term, “Alternative”. However, due to the acronym, another term may need to be considered.

II. Overview of AOAC Standards Development Process – Jim Bradford, CEO AOAC

There is excess revenue from the Research Institute, and it will be reinvested in AOAC INTERNATIONAL Organizational Affiliates’ needs. It was determined that a single harmonized validation system is the need. AOAC will bring together all the players to discuss. Confirmative assessment is what AOAC does. Standard method development is what we do. schematic representation supplied. The Advisory Panel needs to tell us, “who”, from different; organizations, industry, and government, that should be named as Stakeholder Panel participants. These would be “Key Players from around the world” that will be voting members. The AOAC INTERNATIONAL Official Method Board OMB will vest names given. These people will approve voluntary consensus. They will be responsible to come-up with an agreed strategy as the final global goal.

III. Discussion of Purpose and Scope of Project:

Chairman Flowers opened the discussion with allowing each member to voice their input as to the needs and goal of the days project. Input ranged from wanting a core standard that would be flexible enough for universal acceptance, while allowing different analytes and situations to be tweaked by country. All keeping in mind

affordability to the end-user. Other concerns were for adequate representation from not just USA based regulatory agencies, industry, academic and organizations, but a global representation for these categories.

The Panel agreed that FDA and USDA need to be engaged not only with the AOAC and this global effort, but with each other as well. There needs to be a new attitude among all participants, from “us versus them” to “what makes our methods similar, what makes our methods different, and how can we work to find a core standard so that major Standards can all be accepted”. An International Standard and Guideline needs to be the goal with a re-engagement from AOAC to ISO meetings. This would help relate ISO committee with our process. The end goal is to harmonize how the validations are being performed. It doesn’t matter what the name of the validation would be. It is the recognition that is required. A Consensus Method.

Other concerns from the Panel were that AOAC may fall into a trap of “re-inventing” a Standard. That was not the purpose to the meeting. The ISO 16140 was the International Standard. What was proposed was that the United States Government needs to investigate how the International Governments handle standards. The European states are mandated to use ISO standards. The validating parties, MicroVal & AFNOR, will perform the review and the mandated stamp of approval will be applied.

There are many questions that need to be discussed further. Is there a need for equivalency testing of reference methods? There are many methods currently being used that have been validated by several Standards. There is concern from the Panel regarding a proposal of a pilot study. Equivalency data is currently available. How can the equivalency of Standards, starting with ISO and AOAC, be accepted by the community and more importantly, FDA & USDA? How can USDA be persuaded or mandated to cease development of their own methods?

The Draft Purpose & Scope was determined to read as:

Draft Purpose & Scope: Develop Harmonized internationally accepted standard validation schemes for chemical and microbiological analytical methods for food environments and environmental testing.

The Draft Objective was determined to read as:

Draft Objective:

Reach mutual international consensus on analytical method validation protocols to achieve optimal efficiency and avoid duplication of efforts.

IV. Development of stakeholder list for SPAM

- Industry
- Governments
- Organizations
- Academia

V. Priority projects to be undertaken by SPAM in 2011

- Micro Guidelines / consensus on global harm. Or conc. on micro. validation.
 - i. Fit-for-purpose validation
- Qualitative chemistry guidelines; ie. mycotoxins, allergens.

VI. Recommendation for Working Group WG Chair and members for each priority project

- WG for Microbiology: Russ Flowers
- WG for Chemistry: Mark Coleman

Possibility of co-chairs: Government & Industry with International representation.
Working Group chairs will be recruited and may be used in a mediator capacity.

Micro WG Concept Meeting: Goal to define specific agenda.

Paul In'tVeld, Bertrand Lombard, Irene Canada, Evans/Cook, T. Hammack, Palmer Orlandi, FERN, Australian representative, Roger Cook-New Zealand, Stephanie+/Adrian-Nestle, Laura Mout -MicroVal , Neil Apple-Tyson, Method Developer TBD 1- America/1-International, Jim Agin.

Chemistry WG Concept Meeting: Goal to define specific agenda.

Mark Mozola, Patti Meinhardt/Kurt Johnson, more to be determined Mark C., Sam Godfrey, Shani Smith.

It was noted that there were no qualitative chemistry guidelines. This will need to be considered during working group discussions.

Advisory Panel reviewed a plan for the first meeting. Prior to the first meeting, Chair Flowers would like to identify a core group that would be willing to serve as Chairs to the working groups. It was determined that presentations will need to be discussed and planed prior to the first meeting. Topics to define the guideline challenges between ISO and AOAC microbiology Standards. The similarities and differences between the

guidelines. This will be done by conference calls. Perhaps, someone neutral would be best to make presentation. Chemistry guideline development will be discussed with the hope of creating a standard that would assist study directors globally.

VII. Number of SPAM meetings and meeting dates for 2011

Only one meeting was tentatively planned. Telephone conferences are planned for the Working Group Concept meetings. The Stakeholder kick-off meeting is tentative for June, 29th, Wednesday, just after the AOAC BOD meeting scheduled for June 27-28, 2011 in Gaithersburg, MD.

VIII. No other business was brought to the table.

Adjournment 2:15 pm.