



STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

MEETING HELD AT

Washington DC/Rockville Hotel & Executive Meeting Center
Rockville, MD

Tuesday, March 12, 2013

STAKEHOLDER PANEL MEETING PROCEEDINGS

Stakeholder Attendees:

Martin Alewijn, <i>RIKILT</i>	Robert Rankin, <i>IFC</i>
John Austad, <i>Covance Laboratories</i>	Kate Rimmer, <i>NIST</i>
Brad Barrett, <i>AB SCIEX</i>	Joe Romano, <i>Waters Corp.</i>
Sneh Bhandari, <i>Silliker Laboratories</i>	Steve Royce, <i>Agilent Technologies, Inc.</i>
Michael Brodsky, <i>Brodsky Consultants</i>	Karen Schimpf, <i>Abbott Nutrition</i>
Anita Burgher, <i>Pfizer Nutrition</i>	Brooke Schwartz, <i>Schwartz Consulting</i>
Esther Campos-Giménez, <i>Nestlé</i>	Kathy Sharpless, <i>NIST</i>
Scott Christiansen, <i>Perrigo Nutritionals</i>	Li Sheng, <i>EPL Bio Analytical Services</i>
Bob Clifford, <i>Shimadzu</i>	Matt Sliva, <i>Perrigo Nutrition</i>
Jo Marie Cook, <i>Fl. Dept. of Ag & Consumer Services</i>	Karla Steele, <i>Mead-Johnson Nutritional</i>
Jonathan DeVries, <i>Medallion Labs/Gen. Mills</i>	Darryl Sullivan, Chair, <i>Covance Laboratories</i>
Jaap Evers, <i>ISO Rep. (Fonterra Coop.)</i>	John Szpylka, <i>Silliker Laboratories</i>
Ping Feng, <i>Pfizer Nutrition</i>	Joe Thompson, <i>Abbott Nutrition</i>
Brendon Gill, <i>Fonterra</i>	Linda Thompson, <i>Abbott Nutrition</i>
Don Gilliland, <i>Abbott Nutrition</i>	Wayne Wargo, <i>Abbott Nutrition</i>
Qian Graves, <i>FDA</i>	Wayne Wolf, <i>USDA (Retired)</i>
Greg Jaudzems, <i>Nestlé</i>	Jinchuan Yang, <i>Waters Corp.</i>
George Joseph, <i>AsureQuality</i>	
Jim Harnly, <i>USDA</i>	<u>AOAC Staff including:</u>
Greg Hostetler, <i>Perrigo Nutrition</i>	Delia Boyd
Min Huang, <i>Aegis Corp.</i>	E. James Bradford
Wesley Jacobs, <i>Abbott Nutrition</i>	Scott Coates
Erik Konings, <i>Nestlé</i>	Arlene Fox
Stephen Lock, <i>AB SCIEX</i>	Dawn Frazier
Frederic Martin, <i>Nestlé</i>	Nora Marshall
Adrienne McMahon, <i>Pfizer Nutrition</i>	Alicia Meiklejohn
Shang-Jing Pan, <i>Abbott Nutrition</i>	Tien Milor
Melissa Phillips, <i>NIST</i>	Anita Mishra
Shay Phillips, <i>Mead-Johnson Nutritional</i>	Robert Rathbone
Jeanne Rader, <i>FDA</i>	Gar Riegler

I. WELCOME/INTRODUCTIONS

Jim Bradford (AOAC)/Darryl Sullivan (Covance), Chair of the Stakeholder Panel on Infant Formula and Adult Nutrition, introduced and welcomed everyone to the seventh stakeholder meeting of SPIFAN. The voting members in attendance were introduced and recorded for meeting.

II. OUTCOMES FROM EXPERT REVIEW PANEL (ERP) MEETING

Darryl Sullivan (Covance) discussed the Expert Review Panel outcomes and requested the endorsement from the broader stakeholder on the methods chosen for Multi-Lab Testing (MLT). Also, answer any questions pertaining to the ERP meeting.

The Working Group Chairs presented the recommended methods to the Stakeholder Panel for endorsement.

1) Vitamin A/E - Chair – Jon DeVries (Medallion Labs/General Mills)

- ✧ 2012.10 - Simultaneous Determination of Vitamins A, E and Beta Carotene/Mixed Carotenoids in Infant Formula by Normal Phase HPLC. Submitted by Pfizer Nutrition.

Vote: Yes – 9 / No – 1 / Abstain – 4

2) Vitamin B₁₂ - Chair – Esther Campos-Giménez (Nestlé)

- ✧ 2011.10 - Determination of Vitamin B12 in Infant Formula and Adult/Pediatric Nutritional Formula by HPLC. Submitted by Abbott Nutrition.

Vote: Yes – 13 / No – 0 / Abstain – 2

3) Vitamin D - Chair – Don Gilliland (Abbott Nutrition)

- ✧ 2011.11 - AOAC SPIFAN Single Laboratory Validation for Vitamin D Analysis in Infant Formula and Adult Nutritionals and Addendum No. 1a. Submitted by Covance Laboratories.

Vote: Yes – 15 / No – 0 / Abstain – 0

4) Inositol - Co-Chairs – Karen Schimpf (Abbott Nutrition) & Harvey Indyk (Fonterra)

- ✧ 2011.18 - Determination of Myo-inositol in Infant Formula and Adult/Pediatric Nutritional Formula by HPLC Column Switching and Pulsed Amperometry. Submitted by Abbott Nutrition.

Vote: Yes – 15 / No – 0 / Abstain – 0

5) Nucleotides - Chair – Brendon Gill (Fonterra)

- ✧ 2011.20 - Routine Analysis of 5'-Mononucleotides in Infant Formula and Adult/Pediatric Nutritional Formula by Liquid Chromatography. Submitted by Fonterra

Vote: Yes – 11 / No – 0 / Abstain – 4

****RECOMMENDATION:** OMA should reflect the latest version of a method.

III. UPDATE ON THOUGHT LEADER ADVISORY (TLA) MEETINGS

Anita Mishra/Darryl Sullivan provided a report from the Thought Leader Advisory (TLA) meetings held January 31 – February 7, 2013 in Beijing, China and New Delhi, India respectively.

The AOAC delegation which included Mishra, Sullivan and David Acheson met and engaged with key decision makers in both countries. Each ranked their individual priorities and needs; the detailed information provided was discussed among participants of the TLA meetings. ***See full TLA report for details.***

IV. DISCUSSION ON SPIFAN II & FUTURE ACTIVITIES

Robert Rankin (IFC) gave a brief update on the SPIFAN project along with the details and all final activities for SPIFAN I including timelines. In addition, he discussed next steps in the project including the SPIFAN I bridge activities, multi-lab testing, SPIFAN II activities and work on other priority issues identified by stakeholders.

V. REVIEW OF METHOD EVALUATION FORM (Q & A)

Meeting participants/stakeholders discussed the Method Evaluation form and provided input on how to update for future use:

- ◇ Use check box
- ◇ Comparison (actual head to head)
- ◇ Include instrument performance
- ◇ Scaling of the ranking factors (weight)
- ◇ Check the applicability statement
- ◇ Need a summary evaluation on the SMPR if methods do not meet the SMPR
 - May need to update the SMPR
- ◇ Populate form (standardize) to compare data
- ◇ Add target values (if available)
- ◇ Accuracy is most important
 - SRM's – mandatory that the SRM/CRM is analyzed
 - Subtract negative attributes
- ◇ Should proprietary methods be considered?
 - Store Excel spreadsheet for accessibility by the ERP
- ◇ Need chromatogram
- ◇ Where does new technology fit in or get incorporated?