



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

REPORT OF THE EXPERT REVIEW PANEL (ERP) PROCEEDINGS

Expert Review Panel Member Attendees:

Darryl Sullivan, Chair, *Covance Laboratories*
John Austad, *Covance Laboratories*
Sneh Bhandari, *Silliker Laboratories*
Scott Christiansen, *Perrigo Nutritionals*
Jonathan DeVries, *Medallion Labs/Gen. Mills*
Brendon Gill, *Fonterra*
Don Gilliland, *Abbott Nutrition*
Min Huang, *Aegis Corp.*
Erik Konings, *Nestlé*
Adrienne McMahan, *Pfizer Nutrition*
Shay Phillips, *Mead-Johnson Nutritional*
Kate Rimmer, *NIST*
Jeanne Rader, *FDA*
Jinchuan Yang, *Waters Corp.*

AOAC Staff including:

Delia Boyd
E. James Bradford
Scott Coates
Arlene Fox
Nora Marshall
Alicia Meiklejohn
Anita Mishra
Robert Rathbone
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 the participants to Expert Review Panel (ERP) meeting of the SPIFAN project. The ERP members in attendance were introduced.

II. OVERVIEW OF DOWN SELECTION PROCESS & EVALUATION FORM

Erik Konings (Nestlé) provided an overview of the down selection process, rationale and other criteria for completing the Method Evaluation form.

III. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP)

The Expert Review Panel (ERP) discussed the methods and selected a single method for multi-lab testing (MLT) through the SPIFAN process. The following is the result of the discussions and vote.

1) Vitamin A/E

- a. OMA# 2012.09 (VitA-16/VitE-18) & OMA# 2012.10 (VitA-17/VitE-19)
- b. **Score:** 469 points (OMA# 2012.09) / 501 points (OMA# 2012.10)

2) Vitamin B₁₂

- a. OMA# 2011.08 (B₁₂-03) & OMA# 2011.10 (B₁₂-12)
- b. **Score:** 418 points (OMA# 2011.08) / 454 points (OMA# 2011.10)

3) Vitamin D

- a. OMA# 2011.11 (VitD-01) & OMA#2012.11 (VitD-16)
- b. **Score:** 428 points (OMA# 2011.11) / 410 points (OMA# 2012.11)

4) Inositol

- a. OMA# 2011.18 (INOS-34) & OMA# 2012.12 (INOS-39)
- b. **Score:** 493 points (OMA# 2011.18) / 460 points (OMA# 2012.12)

5) Nucleotides

- a. OMA# 2011.20 (Nuc-01) & OMA# 2011.21 (Nuc-02)
- b. **Score:** 493 points (OMA# 2011.20) / 452 points (OMA# 2011.21)

Motion: To advance the selected method for reproducibility study

Method	Method Title	Reviewer(s)	Score	Vote	Recommendations
VitA-16 VitE-18	<i>2012.09 - Simultaneous Determination of 13-Cis and All-Trans Vitamin A Palmitate, Vitamin A Acetate, Alpha Vitamin E Acetate, and Alpha Tocopherol by HPLC and Column Switching. Submitted by Abbott Nutrition. Vitamin A & E Single Laboratory Validation Submitted by Abbott Nutrition.</i>	Scott Christiansen Jinchuan Yang	469		
VitA-17 VitE-19	<i>2012.10 - Simultaneous Determination of Vitamins A, E and Beta Carotene/Mixed Carotenoids in Infant Formula by Normal Phase HPLC. Submitted by Pfizer Nutrition.</i>	Erik Konings Kathy Sharpless/Kate Rimmer	501	Motion: Sneh Bhandari Scott Christiansen Vote: Yes- 9/ No-0 /Abstain-5	<ul style="list-style-type: none"> ◇ Study director to continue with accuracy for each of the matrices. ◇ Need to change in SMPR back from .7 mcg to 7 mcg on the ERP score sheet
VitB₁₂-03	<i>2011.08 - Determination of Vitamin B12 in Infant Formula and Adult/Pediatric Nutritional Formula by Optical Biosensor Protein-Binding Assay. Submitted by Nestlé.</i>	Scott Christiansen Estela Kneeteman	418		<ul style="list-style-type: none"> ◇ Question about Proprietary immune affinity column information
VitB₁₂-12	<i>2011.10 - Determination of Vitamin B12 in Infant Formula and Adult/Pediatric Nutritional Formula by HPLC. Submitted by Abbott Nutrition.</i>	Jon DeVries Shay Phillips	454	Motion: Scott Christiansen John Austad Vote: Yes- 9/ No-0 /Abstain-4	<ul style="list-style-type: none"> ◇ More spike recoveries
VitD-01	<i>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</i>	Brendon Gill Sneh Bhandari	428	Motion: Sneh Bhandari Erik Konings Vote: Yes- 9/ No-0 /Abstain-4	<ul style="list-style-type: none"> ◇ Indicate the sample size ◇ Update method with C30 column. Data collected on modified method. ◇ No issue on D2
VitD-16	<i>2012.11 - Simultaneous Determination of Vitamin D3 and D2 by ESI LC-MS/MS. Submitted by Abbott Nutrition</i>	Jeanne Rader Guenther Raffler	410		

Inos-34	<i>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</i>	Brendon Gill Harvey Indyk	493	Motion: Sneh Bhandari Jon DeVries Vote: Yes- 10/ No-0 /Abstain-3	
Inos-39	<i>2012.12 - Analysis of Free and Total myo-Inositol in Foods, Feeds, and Infant Formula by HPAEC-PAD Including a Novel Total Extraction Using Microwave-Assisted Acid Hydrolysis and Enzymatic Treatment. Submitted by Covance Lab</i>	Brendon Gill Karen Schimpf	460		
Nuc-01	<i>2011.20 - Routine Analysis of 5'-Mononucleotides in Infant Formula and Adult/Pediatric Nutritional Formula by Liquid Chromatography. Submitted by Fonterra</i>	Sneh Bhandari Estela Kneeteman	493	Motion: Sneh Bhandari Don Gilliland Vote: Yes- 9/ No-0 /Abstain-4	◇ Modify to incorporate starch based products ◇ Need to see additional recovery
Nuc-02	<i>2011.21. Submitted by Kinjo Gakin Univ. (Nestlé)</i>	Adrienne McMahon Min Huang	452		

***Include starch with all other methods going forward.**