



# STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

## DRAFT PROCEEDINGS

### Meeting held at:

Boca Raton Resort & Club  
501 East Camino Real  
Boca Raton, FL 33432



BOCA RATON  
RESORT & CLUB

## Saturday, September 6, 2014

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**Saturday, September 6, 2014**

### STAKEHOLDER PANEL/WORKING GROUP MEETING PROCEEDINGS

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#### Stakeholder Attendees:

John Austad, <i>Covance Laboratories</i>	Pierre-Alain Golay, <i>Nestlé</i>
Sean Austin, <i>Nestlé Research Center</i>	Phillip Haselberger, <i>Abbott Nutrition</i>
Stan Bacler, <i>Health Canada</i>	Melissa Holskey, <i>Abbott Nutrition</i>
Brad Barrett, <i>AB Sciex</i>	Steve Holroyd, <i>Fonterra Co-op. - IDF Rep.</i>
Sneh Bhandari, <i>Silliker Labs</i>	Gregory Hostetler, <i>Perrigo/PBM Nutritionals</i>
Christopher Blake, <i>Nestlé Research Center</i>	Min Huang, <i>Frontage Labs, Inc.</i>
Joe Boison, <i>CFIA</i>	Harvey Indyk, <i>Fonterra Co-op.</i>
Amy Brown, <i>FL Dept. of Agriculture</i>	Wesley Jacobs, <i>Abbott Nutrition</i>
Martin Bucknall, <i>UNSW</i>	Greg Jaudzems, <i>Nestlé</i>
Esther Campos-Giménez, <i>Nestlé Research Center</i>	Elaine Jobgen, <i>Eurofins</i>
Nick Cellar, <i>Abbott Nutrition</i>	George Joseph, <i>AsureQuality</i>
Marti Cenky, <i>Abbott Nutrition</i>	Bert Klarenbeek, <i>FrieslandCampina Domo</i>
Scott Christiansen, <i>Perrigo/PBM Nutritionals</i>	Estela Kneeteman, <i>INTI</i>
Robert Clifford, <i>Shimadzu</i>	Khammawan Kohler, <i>Covance Laboratories</i>
Mark Collison, <i>Archer Daniels Midland Co.</i>	Erik J. M. Konings, <i>Nestlé Research Center</i>
Hans Cruijisen, <i>FrieslandCampina Domo</i>	Marcus Lacorn, <i>R-Biopharm AG</i>
Brian De Borba, <i>Thermo Fisher Scientific</i>	Li Xian Liang, <i>China ChongQing CIQ</i>
Jean-Luc Deborde, <i>SCL Laboratoire de Strasburg</i>	Stephen Lock, <i>AB Sciex</i>
Rachel de Guzman, <i>Mead Johnson</i>	E. Marley, <i>R-Biopharm Rhome Ltd. Scotland</i>
Marieke de Laat, <i>Mead Johnson</i>	Frederic Martin, <i>Nestlé Research Center</i>
XiaoJun Deng, <i>SHCIQ</i>	Adrienne McMahon, <i>Wyeth Nutrition</i>
Marcel deVreeze, <i>NEW/ISO</i>	Melissa Meaney Phillips, <i>NIST</i>
Aurélie Dubois-Lozier, <i>IDF</i>	Josh Messerly, <i>Eurofins</i>
Wayne C. Ellefson, <i>Covance Laboratories</i>	Deepali Mohindra, <i>Thermo Fisher Scientific</i>
Milda Embuscado, <i>McCormick</i>	Nancy Montgomery, <i>Abbott Nutrition</i>
Jaap Evers, <i>Fonterra Co-op. – ISO/IDF Rep.</i>	Mardi Mountford, <i>IFC</i>
Ping Feng, <i>Consultant</i>	Norriel Nipales, <i>Wyeth Nutrition</i>
Jennifer Fruth, <i>Mead Johnson</i>	Maria Ofitserova, <i>Pickering Laboratories, Inc.</i>
Brendon D. Gill, <i>Fonterra Co-op.</i>	Lawrence Pacquette, <i>Abbott Nutrition</i>

Shang-Jing Pan, *Abbott Nutrition*  
Shay Phillips, *Mead Johnson Nutrition*  
Eric Poitevin, *Nestlé Research Center*  
Al Poland, *AOAC Consultant*  
Robert Rankin, *IFC*  
Lars Reimann, *Eurofins*  
John Reuther, *Eurofins*  
Catherine A. Rimmer, *NIST*  
Joe Romano, *Waters Corporation*  
Steve Royce, *Agilent Technologies, Inc.*  
Louis Salvati, *Abbott Nutrition*  
Dan Schmitz, *Abbott Nutrition*  
Jeffrey Shippar, *Covance Laboratories*  
Matthew Sliva, *Perrigo/PBM Nutritionals*  
Angela Song, *Abbott Nutrition*  
Karla Steele, *Mead Johnson Nutritionals*

Darryl Sullivan, *Covance Laboratories*  
John Szpylka, *Silliker*  
Joseph J. Thompson, *Abbott Nutrition*  
Linda Thompson, *Abbott Nutrition*  
Melissa Thompson, *Covance Laboratories*  
Laszlo Torma, *Pickering Laboratories, Inc.*  
Marina Torres Rodriguez, *LATU*  
Martijn Vermeulen, *TNO*  
Wayne Wargo, *Abbott Nutrition*  
Laura Wood, *NIST*  
David Woollard, *Hill Laboratories*  
Wayne Wolf, *USDA (Retired)*  
Jinchuan Yang, *Waters Corporation*  
Linda Zhao, *Abbott Nutrition*  
Yang Zhou, *Eurofins*  
Richard Zywicki, *Covance Laboratories*

**AOAC Staff in Attendance**

Delia Boyd  
Jim Bradford  
Scott Coates  
Arlene Fox  
Deborah McKenzie  
Alicia Meiklejohn  
Tien Milor  
Anita Mishra  
Bob Rathbone

**SPIFAN CHAIR**

Darryl Sullivan, *Covance Laboratories*

**SPIFAN II Nutrient Working Group Chairs (5<sup>th</sup> set of nutrients):**

Ping Feng, <i>Consultant</i>	Amino Acids
Wes Jacobs, <i>Abbott Nutrition</i>	Amino Acids
Greg Hostetler, <i>Perrigo/PBM Nutritionals</i>	Carotenoids
Chris Blake, <i>Nestlé Research Center</i>	Chloride & Fluoride

**SPIFAN II Nutrient Working Group Chairs (6<sup>th</sup> set of nutrients):**

Louis Salvati, <i>Abbott Nutrition</i>	Vitamins B <sub>1</sub> , B <sub>2</sub> , B <sub>3</sub> & B <sub>6</sub>
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## 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 tenth stakeholder meeting of SPIFAN. The voting members in attendance were introduced and recorded for meeting.

## II. SPIFAN OVERVIEW

Darryl Sullivan (Covance) updated stakeholders with an overview of the accomplishments and achievements in SPIFAN II, provided background information on the SPIFAN project, and current SPIFAN activities during the AOAC Annual Meeting & Exposition.

## III. SPIFAN WORKING GROUP CHAIR PRESENTATIONS AND VOTE ON FINAL SMPR DOCUMENT

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

SMPRs can be found at the following location: <http://stakeholder.aoc.org/SPIFAN/smpr.html>.

### 1. Amino Acids SMPR (version 2) – *Co-Chairs – Ping Feng (Consultant) & Wes Jacobs (Abbott Nutrition)*

- Remove TMU information, not consistent with other AOAC SPIFAN SMPRs
- Line # 62 - \* (asterisk) – states determine as free Amino Acids, but applicability states free and/or total
- Add reconstitution rate
- Add values in reference materials
- Change table format to be consistent
- Change accuracy to “recovery”

MOTION to approve the Amino Acids SMPR based on the stakeholder discussion: *Sneh Bhandari moved and Bert Klarenbeek second*

**Vote:** Unanimous

### 2. Carotenoids SMPR - *Chair – Gregory Hostetler (Perrigo/PBM Nutritionals)*

- Remove TMU information; not consistent with other AOAC SPIFAN SMPRs
- Add Lutein to SMPR
- Add notation – change definition of Lutein
- Use complete name & CAS #
- Add trans & cis isomers
- Include IUPAC name
- Footnote - include LOQ

MOTION to approve the Carotenoids SMPR with the modifications: *Matt Sliva moved and Sneh Bhandari second*

**Vote:** Yes – 23 / No – 0 / Abstain – 1

### 3. Chloride SMPR - Chair – Christopher Blake (Nestlé)

- Remove TMU information; not consistent with other AOAC SPIFAN SMPRs
- Footnote

MOTION to approve the Chloride SMPR: *Brendon Gill moved and Shay Phillips second*

**Vote:** Unanimous

### 4. Fluoride SMPR - Chair – Christopher Blake (Nestlé)

- Keep recovery range consistent with other AOAC SPIFAN SMPRs

MOTION to approve the Fluoride SMPR: *Shay Phillips moved and John Austad second*

**Vote:** Unanimous

## IV. SPIFAN WORKING GROUP CHAIR LAUNCH PRESENTATION INCLUDING FITNESS FOR PURPOSE

The Working Group Chair Louis Salvati (Abbott Nutrition) presented information and provided the background on the following nutrients including the Fitness for Purpose to the Stakeholder Panel for endorsement: Vitamin B<sub>1</sub>, B<sub>2</sub>, B<sub>3</sub> and B<sub>6</sub>. [Click here](#) to view launch presentation.

## V. UPDATE ON ISO/IDF/AOAC ACTIVITIES

Erik Konings (Nestlé) and Steve Holroyd (Fonterra) provided an update on the AOAC/ISO cooperative and IDF respectively. The ISO/AOAC cooperative was signed in June 2012; the existing cooperation also involves IDF.

Two groups ISO/TC34/WG14 (Vitamins, Carotenoids and Other Nutrients) and ISO/TC34/SC5 (Milk and Milk Products) are involved with establishing ISO standards for the AOAC SPIFAN methods. The ISO working group will be meeting on September 11, 2014 in Boca Raton, FL. The objectives of this working group is to initiate the ISO process for methods on vitamin A/E, vitamin B<sub>12</sub>, and vitamin D; compare generated data for CEN standards and SPIFAN methods on SPIFAN materials and evaluate draft SMPRs for vitamins B<sub>1</sub>, B<sub>2</sub>, B<sub>3</sub> and B<sub>6</sub>.

In summary, ISO/IDF recommends AOAC SPIFAN Final Action methods to become ISO Draft International Standards for vitamin A/E, D and B<sub>12</sub>; the ISO/IDF draft International Standard on Fatty Acids recommended as an AOAC Final Action method; the ISO/IDF draft standard on minerals submitted into the SPIFAN process and foreseeing a closer relationship being built with AOAC relating to milk & milk products.

## VI. UPDATE ON MULTI-LAB TESTING & MATRICES WORKING GROUP

Robert Rankin, (International Formula Council (IFC)) provided an update on multi-lab testing (MLT) activities and the matrices working group. MLT studies are a modified collaborative study in the AOAC SPIFAN process. The manufacturers agreed that along with single laboratory validation (SLV) data demonstrate precision on First Action methods through reproducibility. The process was initiated by IFC with the logistical assistance by Covance Laboratories who is coordinating the shipping of the samples. Additional assistance was provided by AOAC including staff, the Methods Committee on Statistics and the Official Methods Board (OMB). IFC wishes to thank Erik Konings, Jaap Evers, Sneh Bhandari and Darryl Sullivan for their help in reviewing the information as well as the protocols.

The MLT studies follow the AOAC guidelines for collaborative studies as well as the input from ISO and IDF perspective as it relates to statistical requirements. The goal is to select one (1) AOAC First Action method per analyte and that method will go through MLT. We are also currently in the process of picking a back up method in the event something happen with the selected method.

Seven (7) sets of data from the following nutrients (Fatty Acids, Vitamins A/E, Ultra Trace Minerals, Vitamin D, Vitamin B<sub>12</sub>, Inositol and Nucleotides) have been collected and submitted for review by the Expert Review Panel (ERP). The MLT data will also be reviewed through the ISO process and Final Action methods with support from AOAC, ISO/IDF and others will be proposed to Codex as Type II dispute resolution methods. Current studies underway include Iodine, Pantothenic Acid, Vitamin C and Choline. Contact study authors for additional information at

The current project timeline includes the ERP review of seven (7) MLT data as stated above. For March 2015, the ERP is slated to review the MLT data from Iodine, Pantothenic Acid, Vitamin C and Choline. September 2015, March 2016 and September 2016 the ERP will review MLT data from additional studies from the 4<sup>th</sup>, 5<sup>th</sup> and 6<sup>th</sup> set of priority nutrients.

#### **MATRICES WORKING GROUP UPDATE**

Robert Rankin provided an update on the Matrices working group. The Working Group includes the chair Wayne Wargo (Abbott Nutrition) along with the SPIFAN Chair, IFC and representatives from Abbott Nutrition, Mead Johnson, Nestlé, Perrigo, FrieslandCampina. The background on the working group was presented. The manufacturers produced twelve (12) sample matrices for SPIFAN I Activities including SLV, MLT, etc. [Click Here](#) for a list of the AOAC SPIFAN matrices.

For AOAC SPIFAN II, the same products developed for SPIFAN I along with some additional matrices including SPIFAN II analytes when possible (FOS/GOS, carotenoids, fluoride, etc.). Health certificates will accompany all products. Planned availability for AOAC SPIFAN II matrices is November 2014.

### **WORKING GROUP MEETING PROCEEDINGS**

#### **I. WELCOME/INTRODUCTIONS**

Darryl Sullivan (Covance), Chair of the Stakeholder Panel on Infant Formula and Adult Nutrition (SPIFAN) introduced and welcomed everyone to the working group meeting and introduced Louis Salvati as the Working Group Chair.

#### **II. SPIFAN REVIEW AND REACH CONSENSUS ON STANDARD METHOD PERFORMANCE REQUIREMENT (SMPR) DOCUMENTS**

Louis Salvati (Abbott) led the working group discussions on the 6<sup>th</sup> set of priority nutrients: Vitamin B<sub>1</sub>, B<sub>2</sub>, B<sub>3</sub> and B<sub>6</sub>.

Click to view the draft SMPR:

1. [Vitamin B<sub>1</sub>](#) (Thiamin)
2. [Vitamin B<sub>2</sub>](#) (Riboflavin)
3. [Vitamin B<sub>3</sub>](#) (Niacin)
4. [Vitamin B<sub>6</sub>](#) (Pyridoxine)