



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

## **DRAFT PROCEEDINGS**

### **Meeting held at:**

**Gaithersburg Marriott Washingtonian Center**  
9751 Washingtonian Boulevard  
Gaithersburg MD 20878, USA

## **Wednesday, March 14, 2018**

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## STAKEHOLDER PANEL MEETING PROCEEDINGS

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### SPIFAN CHAIR

Darryl Sullivan, Covance Laboratories

### **Stakeholder Attendees:**

Lei Bao, <i>Nestlé</i>	Joanne Mayer, <i>ADM</i>
Charles Barber, <i>NIST</i>	Sean McClure, <i>Abbott Nutrition</i>
Sneh Bhandari, <i>Mérieux NutriSciences</i>	Josh Messerly, <i>Eurofins</i>
Sara Bryson, <i>Conagra Brands</i>	Maria Ofitserova, <i>Pickering Laboratories</i>
Dominik Burger, <i>DSM Nutritional Products</i>	Shay Phillips, <i>Mead Johnson</i>
Esther Campos Gimenez, <i>Nestlé</i>	Melissa Phillips, <i>NIST</i>
Scott Christiansen, <i>Perrigo</i>	Robert Rankin, <i>INCA</i>
Bob Clifford, <i>Shimadzu</i>	Robert-Jan Raterink, <i>Triskelion B.V.</i>
Hans Cruijssen, <i>FrieslandCampina</i>	Joe Romano, <i>Waters Corporation</i>
Marcel de Vreeze, <i>NEN - ISO</i>	Andre Santos, <i>Agilent Technologies, Inc.</i>
Jennifer Donelson, <i>VUV Analytics</i>	Tom Seipelt, <i>Abbott Nutrition</i>
Aurelie Dubois, <i>International Dairy Federation</i>	Aubrey Shahriari, <i>FDA</i>
Jaap Evers, <i>IDF</i>	David Singer, <i>GERSTEL</i>
Ping Feng, <i>Wyeth/Nestlé</i>	Dustin Starkey, <i>Abbott Nutrition</i>
Steven Gendel, <i>USP</i>	Cheryl Stephenson, <i>Eurofins</i>
Brendon Gill, <i>Fonterra Co-Operative Group Ltd</i>	John Szpylka, <i>Mérieux NutriSciences</i>
Ashley Green, <i>NIST</i>	Jeanice Thomas, <i>NIST</i>
Philip Haselberger, <i>Abbott Nutrition</i>	Marina Torres, <i>LATU</i>
Ruth Ivory, <i>Megazyme</i>	Martine van Gool, <i>FrieslandCampina</i>
Greg Jaudzems, <i>Nestlé</i>	Martijn Vermeulen, <i>CCIC Europe</i>
George Joseph, <i>ASURE Quality New Zealand</i>	Wayne Wargo, <i>Abbott Nutrition</i>
Estela Kneeteman, <i>INTI</i>	Laura Wood, <i>NIST</i>
Erik Konings, <i>Nestlé Research Centre</i>	Sudhakar Yadlapalli, <i>First Source Laboratory Solutions, LLP</i>
Joe Konschnik, <i>Restek Corporation</i>	Jinchuan Yang, <i>Waters</i>
Mary Krogull, <i>Eurofins Scientific, Inc.</i>	Jupiter Yeung, <i>Nestle Nutrition</i>
Sookwang Lee, <i>FDA</i>	Joyce Zhu, <i>Jamieson Wellness</i>
Kai Liu, <i>Eurofins Nutrition Analysis Center</i>	
Elaine Marley, <i>R-Biopharm Rhone Ltd</i>	

**AOAC Staff in Attendance**

Delia Boyd

Scott Coates (CSO)

Jennifer Diatz

Arlene Fox

Jonathan Goodwin (*Interim Executive  
Director*)

Nora Marshall

Krystyna McIver

Deborah McKenzie

Alicia Meiklejohn

Tien Milor

La'Kia Phillips

Bob Rathbone

## I. WELCOME/INTRODUCTIONS

Darryl Sullivan (Covance) chair of the AOAC SPIFAN stakeholder panel and President DeAnn Benesh (3M), welcomed participants to the seventeenth stakeholder meeting of AOAC Stakeholder Panel on Infant Formula and Adult Nutrition (SPIFAN) and led the introductions of attendees. The AOAC policy and procedures were also discussed.

## II. UPDATE ON AOAC SPIFAN THOUGHT LEADER ADVISORY MEETING

Alicia Meiklejohn (AOAC) updated the stakeholders on the Thought Leader Advisory (TLA) which was held on February 15, 2018 at AOAC Headquarters. The meeting highlighted common international objectives, current priorities and challenges including export. Other discussions included the AOAC, ISO, and the International Dairy Federation (IDF) tripartite agreement. The original AOAC and ISO agreement was signed on June 18, 2012 with IDF joining thereafter. AOAC also showcased SPIFAN's success and expounded on the current stakeholder process. Meeting participants comprised of AOAC Board members and staff, representatives from INCA, the dairy industry, and infant formula manufacturers.

## III. UPDATE ON INTERNATIONAL ACTIVITIES

### a. **CODEX REVIEW AND ADOPTION OF AOAC SPIFAN METHODS**

Robert Rankin (INCA) provided an update of the Codex process to date which included background information, future considerations, next steps, and proposed methods for other Codex standards.

The SPIFAN Codex Strategy Group continues to develop supporting materials and conducts outreach to key delegations on joint AOAC/ISO/IDF methods submitted to Codex.

The Codex process includes the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) which refers methods to the Codex Committee on Methods of Analysis and Sampling (CCMAS) to conduct technical review/typing, endorses methods and refers those methods to Codex Alimentarius Commission (CAC) for adoption.

As stated in previous updates, there are currently ten (10) AOAC SPIFAN methods in the Codex process as Type II dispute resolution methods:

- Vitamin A
- Vitamin E
- Vitamin C
- Vitamin B12
- Pantothenic Acid
- Myo-inositol
- Fatty Acid Profile
- Total Nucleotides
- Iodine
- Chromium/Molybdenum/Selenium

In December 2017, Vitamin D, Biotin, and Chloride were introduced at CCNFSDU and referred to CCMAS.

In May 2018, CCMAS will review methods for technical review and typing. In July 2018, methods will go to CAC for adoption if CCMAS endorses.

The following will be reviewed in May 2018:

- Biotin – as New Type II; reclassify existing Type II as Type III
- Vitamin D – as New Type II; reclassify existing Type II as Type III and propose existing Type III methods for removal
- Chloride – as New Type II (currently no existing Type II methods)

**b. AOAC/ISO/IDF COOPERATIVE UPDATE**

The cooperative update was presented by Marcel de Vreeze (NEN & ISO) with collaboration from Erik Konings (Nestlé) and Jaap Evers (Fonterra). The agreement is to collaborate with AOAC on standards development for harmonization.

The update included work items for ISO TC 34/WG14 and SC 5|IDF for Biotin, Folate, and Carotenoids. The Vitamin D and Chloride methods will be available as ISO/DIS with the next submission to CCNFSDU.

In addition, the tripartite agreement was discussed with the scope extended beyond infant formula. A draft has been circulated to ISO/TC 34 and subcommittees with positive outcomes, with the exception of microbiological methods. The terms of the agreement will be reviewed on a case-by-case basis to further align and synchronize procedures.

The ISO/TC 34/WG 14 met during the AOAC Mid-Year meeting on Thursday, March 15, 2018 in Gaithersburg, MD and ISO/TC 34/ SC 5|IDF is currently scheduled to meet April 23-27, 2018 in Dublin, Ireland.

**IV. NUTRIENT WORKING GROUP UPDATES**

**Amino Acids (not including Tryptophan) - AOAC SMPR® 2014.013/Ping Feng (Wyeth/Nestlé)**

The working group co-chair provided the stakeholder panel with an update on the revision of the SMPR® including the working group outcomes. The working group originally met on November 28, 2017 to review the SMPR®. The table below was discussed and the original three (3) levels were combined to two (2); changes were also made to the reproducibility. During the stakeholder panel meeting discussions ensued pertaining to the changes and after much debate, it was determined that the SMPR® should be revised and was voted to be sent back to the working group.

Recovery	0.4–5.0b	80 - 110%
	>5.0	90 - 110%
Repeatability (RSDr)	0.4–5.0a	≤10%
	> 5.0	≤7%
Reproducibility (RSDR)	0.4–5.0b	≤15%
	> 5.0	≤10%

**Motion:** Wayne Wargo moved and Brendon Gill second to return the SMPR® to the working group for revision.

Yes-21/No-2/Abstain 1 - **Motion passed.**

There was a request to replace the past co-chair (Wes Jacobs, Abbott) with Philip Haselberger also of Abbott.

▪ **Fluoride - AOAC SMPR® 2014.016/Eric Poitevin (Nestlé)**

Erik Konings (Nestlé) on behalf of the working group chair presented the SMPR® to the stakeholder panel as revised by the working group during their meetings held on November 15, 2017 and December 14, 2017. The working group proposed the following:

- 1) Adjust the LOQ from 5 µg / 100g to 30µg / 100g
- 2) Adjust the lower range band [for recovery, RSDr, and RSDR] from 5 – 25 µg / 100g to 30 - 100 µg / 100g
- 3) Adjust the upper range band [for recovery, RSDr, and RSDR] from 100 µg / 100g to 200 µg / 100g

**Motion:** Erik Konings moved and Joe Romano second to accept the SMPR® as presented.

Yes-17/No-1/Abstain 2 - **Motion passed.**

▪ **GOS - AOAC SMPR® 2014.003/Sean Austin (Nestlé)**

Erik Konings (Nestlé) on behalf of the working group chair presented the SMPR® to the stakeholder panel as revised by the working group during their meeting held on November 29, 2017. The working group proposed the following:

- 1) The analytical range was lowered to 0.2–**3.0<sup>b</sup>** from 0.2–5.0<sup>b</sup>
- 2) (β-D-Galp-(1→B))<sub>n</sub>-β-D-Galp-(1→A)-D-Glcp  
(β-D-Galp-(1→B))<sub>m</sub>-D-Galp  
where **n ≥ 0; m ≥ 1** was changed from n = 0-8; m = 1-9  
B = 2,3,4 or 6  
If n>0, A=1,2,3,4 or 6  
If n= 0, A=1,2,3 or 6

**Motion:** Erik Konings moved and Sneh Bhandari second to accept the SMPR® as presented.

Yes-19/No-0/Abstain 1 - **Motion passed.**

**V. UPDATE ON MULTI-LABORATORY TESTING (MLT)**

Robert Rankin (INCA) provided the stakeholders with a status update on the multi-laboratory testing (MLT). Background information included ISO and IDF standards requirements to consist of some form of collaborative study with Codex expecting collaborative study on methods to support Type II status. Fourteen (14) MLT studies have been completed to date and five (5) additional are currently underway with the following nutrients: Choline, B Vitamins (B<sub>1</sub>, B<sub>2</sub>, B<sub>6</sub>), FOS, Tryptophan, and Carotenoids.

**VI. UPDATE ON EXPERT REVIEW PANEL (ERP) STATUS**

Darryl Sullivan (Covance) provided an update to the stakeholder community on the Expert Review Panel (ERP) activities to date along with information on the methods to be reviewed during the meeting including previous methods for B Vitamins (B<sub>3</sub> only).

**VII. TIMELINES/DEADLINES/WRAP-UP**

Darryl Sullivan (Covance) & Alicia Meiklejohn (AOAC) provided a timeline of AOAC SPIFAN activities including upcoming deadlines, wrapped up all discussions and answered any additional questions/comments.