



STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

DRAFT PROCEEDINGS

Meeting held at:

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

Tuesday, March 15, 2016

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STAKEHOLDER PANEL MEETING PROCEEDINGS

Stakeholder Attendees:

Manali Aggrawal, *ThermoFisher Scientific*
John Austad, *Covance Labs*
Sean Austin, *Nestlé Research Centre*
Brad Barrett, *Gerstel*
DeAnn Benesh, *3M FSD*
Patrick Bird, *Q Laboratories*
Joe Boison, *CFIA*
Scott Christiansen, *Perrigo Nutritionals*
Bob Clifford, *Shimadzu*
Hans Cruijssen, *FrieslandCampina*
Marcel deVreeze, *NEN-ISO*
Stefan Ehling, *Abbott Nutrition*
Jaap Evers, *IDF*
James Falk, *USDA, AMS, S & T*
Ping Feng, *Wyeth Nutrition*
Heather Figure, *Healthy Directions*
Andrew Fussell, *PANalytical*
Brendon Gill, *Fonterra Cooperative*
Don Gilliland, *Abbott Nutrition*
Philip Haselberger, *Abbott Nutrition*
Norma Hill, *TTB (Retired)*
Greg Hostetler, *Perrigo Nutritionals*
Wes Jacobs, *Abbott Nutrition*
Greg Jaudzems, *Nestlé USA, Inc.*
Martha Jennens, *Covance*
George Joseph, *AsureQuality*
Estela Kneeteman, *INTI*
Erik Konings, *Nestlé*
Marcus Lacorn, *R-Biopharm*
Kristie Laurvick, *USP*
SooKwang Lee, *FDA*
Qi Lin, *Abbott Nutrition*

Vicky Manti, *Danone*
Elaine Marley, *R-Biopharm Rhone*
Frederic Martin, *Nestlé*
Katerina Mastovska, *Covance*
Mary McBride, *Agilent Technologies*
Adrienne McMahon, *Wyeth/Nestlé*
Josh Messerly, *Eurofins*
Paul Milne, *Keurig Green Mountain*
Bill Mindak, *FDA CFSAN*
Deepali Mohindra, *ThermoFisher Scientific*
Lisa Monteroso, *3M*
Rick Myers, *Kemin*
Greg Noonan, *FDA*
Maria Ofitserova, *Pickering Labs, Inc.*
Lawrence Pacquette, *Abbott Nutrition*
Shang-Jing Pan, *Abbott Nutrition*
Melissa Phillips, *NIST*
Shay Phillips, *Mead Johnson Nutrition*
Curtis Phinney, *Curtis S. Phinney, CNS*
Günther Raffler, *Eurofins/CLF*
Robert Rankin, *INCA*
Pingfan Rao, *CIFST*
Rick Reba, *Nestlé*
Kate Rimmer, *NIST*
Jeff Rohrer, *Thermo Fisher Scientific*
Shauna Roman, *Reckitt Benckiser*
Joe Romano, *Waters Corp.*
Louis Salvati, *Abbott Nutrition*
Andre Schieiber, *SCIEX*
Karen Schimpf, *Abbott Nutrition*
Brooke Schwartz, *Brooke Schwartz Consulting*
Christopher Smith, *Coca-Cola*

Angela Song, *Abbott Nutrition*
Monique Steegmans, *Tienen Miher/Beneo Orafiti*
Karla Steele, *Mead Johnson Nutritionals*
Kathy Stenerson, *Millipore Sigma-Aldrich*
Cheryl Stephenson, *Eurofins*
Joan Stevens, *Agilent Technologies*
John Szpylka, *Mérieux NutriSciences*
Steve Tennyson, *Perrigo Nutritionals*
Joe Thompson, *Abbott Nutrition*
Marina Torres, *LATU*
Socrates Trujillo, *FDA*
Martijn Vermeulen, *Ausnutria Hyproca*

Wayne Wargo, *Abbott Nutrition*
Wayne Wolf, *USDA (Retired)*
Laura Wood, *NIST*
David Woollard, *Eurofins (formerly of Hill Labs)*
Jason Wubben, *ADM*
Dorothy Yang, *Agilent Technologies*
Jinchuan Yang, *Waters Corp.*
Zhou Yao, *SH-CIQ*
William Xue, *Accucaps*
Chunyan Zhang, *Abbott Nutrition*
Joyce Zhu, *Jamieson*
Jerry Zweigenbaum, *Agilent Technologies*

AOAC Staff in Attendance

Delia Boyd
E. James Bradford (Executive Director)
Scott Coates (CSO)
Chris Dent
Arlene Fox
Dawn Frazier

Nora Marshall
Deborah McKenzie
Alicia Meiklejohn
Tien Milor
LaKia Phillips
Bob Rathbone

SPIFAN CHAIR

Darryl Sullivan, Covance Laboratories

I. WELCOME/INTRODUCTIONS

Jim Bradford (AOAC) welcomed everyone to the twelfth stakeholder meeting of AOAC Stakeholder Panel on Infant Formula and Adult Nutrition (SPIFAN) and led introductions of attendees. Bradford then introduced AOAC President Norma Hill who provided brief remarks and then introduced Darryl Sullivan (Covance), chair of AOAC SPIFAN.

II. SPIFAN OVERVIEW

Deborah McKenzie (AOAC INTERNATIONAL) provided background information on the SPIFAN project, provided an historical perspective on infant formula including regulatory challenges, engagement of the infant formula industry and current voluntary consensus standards developments. McKenzie updated stakeholders with an overview of the accomplishments and achievements in SPIFAN II including twenty-nine (29) AOAC Standard Method Performance Requirements (SMPRs®) which included Compound 1080, thirty-three (33) First Action and eight (8) Final Action *Official Methods*SM for nutrients in infant formula along with three (3) First Action *Official Methods*SM for Compound 1080; these included the eight (8) jointly submitted Final Action methods to Codex with ISO and IDF.

III. UPDATE ON INTERNATIONAL ACTIVITIES

a. **UPDATE ON AOAC SPIFAN FINAL ACTION OFFICIAL METHODS OF ANALYSIS**

Darryl Sullivan (Covance) provided an update on the activities related to the submission of the AOAC SPIFAN Final Action methods to the FAO/WHO Codex Alimentarius Commission (CAC). The objectives included AOAC standards development, method evaluation, achievement of AOAC Final Action method status, and publication of method manuscripts. AOAC entered into an agreement with ISO and IDF to participate in each other's work to jointly develop and approve standards.

Methods were presented to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) during their session held November 23-27, 2015 in Bad Soden am Taunus, Germany for endorsement and subsequently forwarded to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for technical review February 22-26, 2016 in Budapest, Hungary.

b. **AOAC/ISO/IDF ACTIVITIES**

Erik Konings (Nestlé & ISO) in collaboration with IDF provided an update on the AOAC/ISO/IDF activities including the submission of AOAC SPIFAN methods for endorsement by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). November 23, 2015 was the first opportunity to submit the AOAC SPIFAN Final Action methods into the Codex system. Advantages of the submission as AOAC/ISO/IDF is globally harmonized dispute resolution methods which will increase global availability and accessibility.

An AOAC/ISO/IDF delegation participated in the 37th session of the Codex Committee on Methods of Analysis and Sampling (CCMAS) meeting in Budapest, Hungary held February 22-26, 2016. The delegation also participated in the Inter Agency Meeting (IAM) with the objective of eight (8) AOAC SPIFAN methods being endorsed as Type II dispute resolution methods in Codex. CCMAS endorsed analytical methods for six (6) provisions, and recommended the Codex Alimentarius Commission (CAC) adopt the methods as Type II (Dispute resolution) methods. The methods submitted include: Vitamin B₁₂, Pantothenic Acid, Total Nucleotides, Iodine, Fatty Acids and Vitamin A. The method for chromium, selenium and molybdenum was endorsed as Type III with additional questions regarding performance referred back to CCNFSDU.

CCMAS also endorsed analytical methods for Vitamin E and Myo-inositol, and recommended CAC adopt the methods during their meeting in 2017 as Type II, provided that CCNFSDU confirms that the forms to be analyzed according to *CODEX STAN 72-1981* match those analyzed by the respective methods. CCMAS will also inform CCNFSDU that none of the current methods of analysis (whether in the Codex system or not) meet all performance criteria required by *CODEX STAN 72-1981* for Infant formula, but the new proposed methods are the best currently available. CCNFSDU will be asked for further guidance relating to the criteria during their upcoming meeting to be held December 2016.

c. **WHEY PROTEIN: CASEIN RATIO (WPC) UPDATE**

Angela Song (Abbott) provided an update from Ziting Zhang (European Union Chamber of Commerce in China). She provided information on changes in the standard including the use of peptide as standard to using protein.

As part of the timeline of the method of whey protein the standard was approved by the technical review panel of the Standardisation Administration of China in November 2015 and distributed the revised draft standards in January 2016 and was submitted to CFSA in February 2016. The validation report is expected to be completed March 2016, but no final review date has been established.

The next steps include a meeting with the CFSA and the NHFPC in March 2016 to understand their positions with key messages from companies that due to the revision, the standard should be considered a new standard and changing of the standard materials cannot help improve the accuracy of the testing method.

Currently, China is proposing to retest with six (6) labs participating (five (5) Chinese labs and one (1) manufacturers lab) and revise the method. The stakeholders requested that AOAC SPIFAN interact with the process in China and possibly review the validation.

IV. PROFICIENCY TESTING (PT) TASKFORCE – PILOT PROGRAM

Don Gilliland (Abbott) in conjunction with PT Working Group co-chair Melissa Phillips (NIST) provided an update on the Proficiency Testing Pilot Program.

The program will include six (6) laboratories in total with representation from the US and Europe which may/may not include AOAC SPIFAN experience. The methods may include AOAC *Official Methods of AnalysisSM (OMA)* from AOAC SPIFAN. The samples will be distributed late March 2016 with the results due thirty (30) days after receipt.

The timeline included the taskforce meeting with the AOAC SPIFAN stakeholder in September 2015 in conjunction with the AOAC Annual Meeting & Exposition in Los Angeles, CA. The taskforce held regular teleconference meetings from October 2015-February 2016 to develop the structure of the pilot program. In February 2016 the pilot program was distributed to the AOAC SPIFAN stakeholders for comments and was subsequently finalized. In March 2016, the matrices were selected with samples to be shipped to the participating labs with the results expected from participants by May 2016. The final report on the pilot program is expected by June 2016.

V. WORKING GROUP DISCUSSION

Darryl Sullivan (Covance) moderated discussions with the working group chairs on the status of their nutrients for which there are no current AOAC First Action *Official Methods*SM status.

1. **Working Group on Amino Acids**-Ping Feng(Wyeth)/Wes Jacobs (Abbott)
2. **Working Group on Biotin**-George Joseph (AsureQuality)/Jean-Luc Deborde (SCL)
3. **Working Group on B Vitamins (B₃)**-Louis Salvati (Abbott)
4. **Working Group on Carotenoids**-Greg Hostetler (Perrigo)
5. **Working Group on Fluoride**-Chris Blake (Nestlé) – Update information provided by Erik Konings.
6. **Working Group on FOS**-Sean Austin (Nestlé)
7. **Working Group on GOS**-Sean Austin (Nestlé)

Outcome(s):

- Chair of the AOAC SPIFAN Working Group on Carotenoids proposed to re-engage the working group to reconsider the SMPR information for this set of nutrients.

VI. INCA IDEAS FOR FUTURE WORKPLAN

Robert Rankin (INCA) updated the stakeholder panel on future activities for consideration and requested input on pace of work, meeting times and next steps for the project. INCA will also provide feedback from the meeting to AOAC along with a proposed action plan.

VII. TIMELINES/DEADLINES/WRAP-UP

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