



STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

DRAFT PROCEEDINGS

Meeting held at:

**Sheraton Dallas Hotel
400 N. Olive Street
Dallas, TX 75201**

Saturday, September 17, 2016

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STAKEHOLDER PANEL MEETING PROCEEDINGS

SPIFAN CHAIR

Darryl Sullivan, Covance Laboratories

Stakeholder Attendees:

Claude Aebischer, <i>DSM</i>	Phillip Haselberger, <i>Abbott Nutrition</i>
Karen Andrews, <i>USDA</i>	Tony Hitchins, <i>FDA (Retired)</i>
John Austad, <i>Covance</i>	Steve Holroyd, <i>Fonterra</i>
Sean Austin, <i>Nestlé</i>	Melissa Holskey, <i>Abbott Nutrition</i>
Brad Barrett, <i>Gerstel</i>	Greg Hostetler, <i>Perrigo Nutritionals</i>
Sneh Bhandari, <i>Mérieux NutriSciences</i>	Harvey Indyk, <i>Fonterra</i>
Keren Breiterman, <i>Eurofins</i>	Greg Jaudzems, <i>Nestlé USA, Inc.</i>
Amy Brown, <i>FL. Dept. of Agriculture</i>	Holly Johnson, <i>Alkemist</i>
Anton Bzhelyansky, <i>USP</i>	George Joseph, <i>AsureQuality</i>
Hans Cruijisen, <i>FrieslandCampina</i>	Estela Kneeteman, <i>INTI</i>
Kommer Brunt, <i>Rotating Disc</i>	Erik Konings, <i>Nestlé</i>
Michelle Bugayong, <i>Abbott Nutrition</i>	Mary Kay Krogull, <i>Eurofins</i>
Carolyn Burdette, <i>NIST</i>	John Lawry, <i>Covance</i>
Esther Campos-Giménez, <i>Nestlé</i>	John Lee, <i>Agilent Technologies</i>
Liang Cheng Zhu, <i>SDCIQ</i>	SooKwang Lee, <i>FDA</i>
Scott Christiansen, <i>Perrigo Nutritionals</i>	Kai Lin, <i>Eurofins</i>
Bob Clifford, <i>Shimatzu</i>	Adrienne McMahon, <i>Wyeth Nutrition</i>
Ryan Connelly, <i>Covance</i>	Josh Messerly, <i>Eurofins</i>
Jo Marie Cook, <i>FL. Dept. of Agriculture</i>	Dan Meyer, <i>ADPI</i>
Hans Cruijisen, <i>FrieslandCampina</i>	Bill Mindak, <i>FDA</i>
David Dain, <i>DSM</i>	Deepali Mohindra, <i>Thermo Scientific</i>
Jean-Luc Deborde, <i>SCL-France</i>	Mardi Mountford, <i>INCA</i>
Raquel De Guzman, <i>Mead Johnson</i>	Jacob Nielsen, <i>ARLA Foods</i>
Purnima Devi, <i>Synlait</i>	Gregory Noonan, <i>FDA</i>
Renee Erney, <i>Abbott Nutrition</i>	Shay Phillips, <i>Mead Johnson</i>
Ping Feng, <i>Wyeth Nutrition</i>	Eric Poitevin, <i>Nestlé</i>
Christophe Fuerer, <i>Nestlé</i>	Günther Raffler, <i>Eurofins/CLF</i>
Brendon Gill, <i>Fonterra</i>	Robert Rankin, <i>INCA</i>
Rajesh Girdhar, <i>Abbott Nutrition</i>	Rick Reba, <i>Nestlé</i>
Doug Gordon, <i>Abbott Nutrition</i>	Klaus Reif, <i>Phytolab</i>

Joe Romano, *Waters Corp.*
Andre Santos, *Agilent Technologies*
Karen Schimpf, *Abbott Nutrition*
Dan Schmitz, *Abbott Nutrition*
Olga Shimelis, *Millipore Sigma*
Jeff Shippar, *Covance*
Sean Singh, *Synlait*
Saovaros Srichimuttayomphol, *Mead Johnson*
Monique Steegmans, *Tienen Miher/Beneo Orafti*
Kathy Stenerson, *Millipore Sigma*
Cheryl Stephenson, *Eurofins*
Joan Stevens, *Agilent Technologies*
Steve Tennyson, *Perrigo Nutritionals*
John Szpylka, *Mérieux NutriSciences*
Joe Thompson, *Abbott Nutrition*
Linda Thompson, *Abbott Nutrition*
Marina Torres, *LATU*
Harrie van den Bijgaart, *Qlip*

Martine van Gool, *FrieslandCampina*
Jeroen van Soest, *Eurofins*
Martijn Vermeulen, *Ausnutria Hyproca*
Morgan Wallace, *Rheonix*
Wayne Wargo, *Abbott Nutrition*
Laura Wood, *NIST*
David Woollard, *Eurofins NZ*
Chao Wu, *Hilmar Cheese*
Jason Wubben, *ADM*
Sa Xu, *Agropur*
Jinchuan Yang, *Waters Corp.*
Kurt Young, *GNC/Nutra Manufacturing*
Joanie Zhang, *Agropur*
Joseph Zhou, *Sunshineville*
Yang Zhou, *Eurofins*
Jerry Zweigenbaum, *Agilent Technologies*
Richard Zywicki, *Covance*

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
La’Kia Phillips
Al Pohland (Consultant)
Bob Rathbone

I. WELCOME/INTRODUCTIONS

Jim Bradford (AOAC) welcomed everyone to the fourteenth stakeholder meeting of AOAC Stakeholder Panel on Infant Formula and Adult Nutrition (SPIFAN) and led introductions of attendees. Bradford introduced Darryl Sullivan (Covance), chair of AOAC SPIFAN stakeholder panel.

II. SPIFAN OVERVIEW

Darryl Sullivan (Covance) updated the stakeholders with an overview of the accomplishments and 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 development including the AOAC Standard Method Performance Requirements (SMPRs®). Related roles and responsibilities with the various entities including the Official Methods Board (OMB), stakeholder and expert review panels and AOAC staff were also discussed. Activities included the outcomes of the March 2016 mid-year meeting and proposed activities to be held during the AOAC Annual Meeting. A Whey Protein: Casein Ratio update was also provided.

III. UPDATE ON INTERNATIONAL ACTIVITIES

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

Robert Rankin (INCA) and Darryl Sullivan (Covance) provided progress to date on the activities related to the submission of the AOAC SPIFAN Final Action *Official Method*SM to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). Rankin also provided background information including prior submissions into the Codex process. The Next steps will be to submit the AOAC 2012.22 (Vitamin C) method into the Codex system.

b. **UPCOMING CODEX MEETINGS**

Robert Rankin (INCA) updated the stakeholder panel on the future meeting dates and highlighted efforts in preparation for the upcoming Codex committee meetings including CCNFSDU for which AOAC SPIFAN methods may be under consideration. The first meeting will be held December 5-9, 2016 in Hamburg, Germany; additional meetings are slated for 2017.

c. **REVIEW OF AOAC SMPRS AND CODEX STAN 72**

Scott Coates (AOAC) reported on a comparison study document of AOAC SPIFAN SMPRs and the Codex Standard 72 for infant formula to ensure compliance.

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

The cooperative update was presented by Erik Konings (ISO representative) with collaboration from Harrie van den Bijgaart (ISO/IDF) and Marcel de Vreeze (NEN & IDF). The cooperation agreement was signed with AOAC in 2012 to collaborate on standard development for harmonization. The update consisted of activities with AOAC/ISO/IDF to establish the SPIFAN samples. The system is a two way direction on the methods; studies could come into the AOAC process as well as into the ISO/IDF process.

At the beginning of the 2016, several new work item proposals were launched in the ISO/IDF process, which means that as soon as a topic can be shared there will be a work item proposal launched. As recommended at the March 2016 meeting, include the feedback given by ISO/IDF prior to executing the protocols in their respective process and evaluate the study data. Vitamins B₁, B₂, and B₆, vitamin D, vitamin K, carnitine/choline, folate, and biotin were reviewed by the ISO TC 34/WG 14 (Vitamins,

Carotenoids and other nutrients). The working group level discussions included the MLT protocols. ISO TC 34/SC 5 on milk & milk products (IDF) reviewed methods for chloride, minerals, fructans (FOS) and GOS. The agreements are possible for standards to be adopted by different organizations and countries.

e. **UPDATE ON GLOBAL OUTREACH**

Robert Rankin (INCA) focused discussion on facilitating international awareness for the SPIFAN methods by engaging the communities and regions around the world. Focus includes identifying key countries to promote the SPIFAN methods. Ongoing efforts will continue for outreach to continue to Brazil, India, China, and Europe including Codex.

IV. UPDATE ON INFANT FORMULA PROFICIENCY TESTING (PT) PROGRAM TASKFORCE Darryl Sullivan (Covance) provided an update on the Proficiency Testing Pilot Program on behalf of the program co-chairs Don Gilliland (Abbott) and Melissa Phillips (NIST).

The infant formula manufacturers formed a working group (Matrices Working Group) to develop a suite of test materials to use in the validated studies. Currently, in the second reiteration of supplies, the objective is to make the SPIFAN methods widely available as well as test samples. The program is being used as a path forward and work plan to develop a proficiency program for nutrients in infant formula as a resource to the SPIFAN community.

Using the consensus approach, the taskforce pilot program launched with a wide variety of products in the portfolio including those with challenging matrices. It will identify and address the components using the SPIFAN methods which include nutrient definitions and units of measurement per the SMPR[®] identify the product matrices, the testing frequencies in the different type of products used and establish the statistical design. The program will also include instrument detail.

The taskforce also discussed using a consensus true value based on the proficiency program for use on the SPIFAN methods or all methods. The program will test the processes, not the test methods or laboratories; the labs signed up through a submission site. Six (6) labs were chosen and feedback was received from those labs on instructions, overall process and reporting format for the data entry forms. With the pilot program, submission of the laboratory samples will take place within a 30-day timeframe. Assessing data from multiple methods is part of the program.

V. DISCUSSION ON AOAC PROCESSES & PRIORITY NUTRIENTS

Deborah McKenzie (AOAC) provided information on AOAC processes in relation to the development of standards and also reviewed AOAC policies and procedures.

The Working group chairs lead discussions relating to analytical challenges and deficiencies with Carotenoids, Fluoride, and Folic Acid (folate). There is a method currently submitted for carotenoids, but the working group chair requested that the SMPR[®] be split into multiple SMPRs[®] with one measuring only beta carotene and lutein. Lycopene and alpha carotene should have a separate SMPR[®]. Methods should separate alpha carotene (cis and trans isomers), not necessarily quantify.

Folate was also a discussed due to the question that was raised concerning revising the applicability statement in the SMPR[®] to include both folic acid and 5-MTHF (polyglutamate) in determining the total folate.

The fluoride discussion included old, new and alternative methodologies. The Codex requirement for the nutrient was also discussed.

VI. AOAC SPIFAN FUTURE ENDEAVORS

Robert Rankin (INCA) updated the stakeholder community on the potential future activities for AOAC SPIFAN which included progress to date. The proposed action plan includes continuation with the SPIFAN II nutrients through March 2017, with five (5) nutrients without First Action *Official Method*SM status along with Final Action methods and ISO/IDF standards for the remaining nutrients. Currently, we are working to develop objectives for SPIFAN III with the focus on meeting the needs of the community via this forum along with stakeholder financial support of the program/process. Discussions also included Codex adoption of the collaborated methods for all nutrients groups.

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.