



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 15, 2017

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STAKEHOLDER PANEL MEETING PROCEEDINGS

SPIFAN CHAIR

Darryl Sullivan, Covance Laboratories

Stakeholder Attendees:

John Austad, *Covance*

Lei Bao, *Nestlé*

Charles Barber, *NIST*

Sneh Bhandari, *Mérieux NutriSciences*

Amy Brown, *Florida Dept. of Agriculture and Consumer Services*

Esther Campos Giménez, *Nestlé*

Steve Choquette, *NIST*

Scott Christiansen, *Perrigo Nutritionals*

Bob Clifford, *Shimadzu*

Jo Marie Cook, *Florida Dept. of Agriculture and Consumer Services*

Hans Cruijssen, *FrieslandCampina*

Marcel de Vreeze, *NEN ISO*

Jean-Luc Deborde, *SCL*

Jennifer Donelson, *VUV Analytics*

Jaap Evers, *IDF*

Ping Feng, *Wyeth*

Christophe Fuerer, *Nestlé Research Center*

Brendon Gill, *Fonterra Co-operative Group*

Philip Haselberger, *Abbott Nutrition*

Norma Hill, *TTB (Retired)*

Melissa Holskey, *Abbott Nutrition*

Greg Jaudzems, *Nestlé*

George Joseph, *AsureQuality*

Estela Kneeteman, *INTI*

Erik Konings, *Nestlé Research Centre*

Markus Lacorn, *R-Biopharm AG*

Paolo Lecchi, *DSM Nutritional Products*

Sookwang Lee, *FDA*

Alex Liu, *SCIEX*

Vicky Manti, *Danone*

Elaine Marley, *R-Biopharm Rhone Ltd.*

Katerina Mastovska, *Covance*

Mary McBride, *Agilent*

Josh Messerly, *Eurofins*

Bill Mindak, *FDA*

Tracy Mui, *PepsiCo*

Eystein Oveland, *National Institute of Nutrition and Seafood Research*

Lawrence Pacquette, *Abbott Nutrition*

Shay Phillips, *MJN*

Melissa Phillips, *NIST*

Annemieke Pustjens, *RIKILT*

Robert Rankin, *INCA*

Rick Reba, *Nestlé*

John Reuther, *Eurofins CAL*

Joe Romano, *Waters Corporation*

Andre Santos, *Agilent Technologies*

Florian Schweigert, *BioAnalyt GmbH*

Maurice Seegers, *Mead Johnson Nutrition*

Weilin Shelver, *USDA*

Aniko Solyom, *GAAS Analytical*

John Szpylka, *Mérieux NutriSciences*

Steve Tennyson, *Mérieux NutriSciences*
Joe Thompson, *Abbott Nutrition*
Marina Torres, *LATU*
Martine van Gool, *FrieslandCampina*
Martijn Vermeulen, *Ausnutria Hyproca*
Wayne Wargo, *Abbott Nutrition*
Laura Wood, *NIST*
Jason Wubben, *ADM*

Sudhakar Yadlapalli, *First Source Laboratory Solutions, LLP*
Jinchuan Yang, *Waters Corp.*
Xionghai Yi, *Shanghai Exit and Entry Inspection and Quarantine Bureau*
Wei Zhu, *Danone*
Joyce Zhu, *Jameson*
Jerry Zweigenbaum, *Agilent Technologies*

AOAC Staff in Attendance

Delia Boyd
Scott Coates (*CSO*)
Chris Dent
Arlene Fox
Dawn Frazier
Jonathan Goodwin (*Interim Executive Director*)

Nora Marshall
Deborah McKenzie
Alicia Meiklejohn
Tien Milor
La’Kia Phillips
Bob Rathbone

I. WELCOME/INTRODUCTIONS

Darryl Sullivan (Covance), chair of AOAC SPIFAN stakeholder panel welcomed everyone to the fifteenth stakeholder meeting of AOAC Stakeholder Panel on Infant Formula and Adult Nutrition (SPIFAN) and led introductions of attendees. Sullivan introduced Jonathan Goodwin (AOAC Interim Executive Director) to the panel members.

II. SPIFAN OVERVIEW

Darryl Sullivan (Covance) updated the stakeholders with an overview of the accomplishments and provided background information on the SPIFAN project, information included 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®). Activities included the outcomes of the September 2016 annual meeting and proposed activities to be held during the 2017 AOAC Mid-Year Meeting.

III. UPDATE ON INTERNATIONAL ACTIVITIES

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

Robert Rankin (INCA) provided background information including prior submissions into the Codex process and 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). The committee has decided to make Fatty Acid, Vitamins B₁₂ & E and Myo-inositol Type II methods along with the advancement of the Cr/Mo/Se method from Type III to Type II. CCNFSDU also introduced AOAC 2012.22 (Vitamin C) method into the Codex system. The next steps will be for Codex Committee on Methods of Analysis and Sampling (CCMAS) to consider recommendation from CCNFSDU to include the new LOQ data for Cr/Mo/Se method and the SPIFAN argument against criteria method approach and possibly recommend the method as Type II. The next meeting of CCMAS is proposed for May 2017 with the location TBD.

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

The cooperative update was presented by Erik Konings (ISO representative) with collaboration from Jaap Evers (IDF) and Marcel de Vreeze (NEN & ISO). The cooperation agreement was signed with AOAC in 2012 to collaborate on standard development for harmonization.

Update included general publications information on the vitamin D and biotin methods which are currently in review for April 2017 and October 2017 respectively along with Chloride, minerals and trace elements and fructans which will be also be reviewed for publication in April 2017. Carnitine/choline, vitamins B₁, B₂, and B₆, and vitamin K will be reviewed for publications in November 2017 if multi-laboratory testing is completed. Due to the revision of the carotenoids and folate (folic acid) standard method performance requirements (SMPR®), these methods will be reviewed for publications when they become available.

The proposed dates for the next ISO meetings are March 17, 2017 in Gaithersburg, MD (ISO/TC 34/WG 14) and May 8-12, 2017 in Madison, WI (ISO/TC 34/SC5/IDF).

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

Ping Feng (Wyeth) focused discussion on the WPC analysis method and the Chinese national standards (GB) including definitions and background information on regulations for products and how methods enter the process.

IV. NUTRIENT WORKING GROUP UPDATES

Carotenoids & Folate

Greg Hostetler (Perrigo) & Erik Konings (Nestlé) working group chairs presented proposed revisions by their respective working groups to update the Standard Method Performance Requirements (SMPR®) for the Determination of Selected Carotenoids in Infant and Adult/Pediatric Nutritional Formula (AOAC SMPR 2014.014) and Folate in Infant Formula and Adult/Pediatric Nutritional Formula (AOAC SMPR 2011.006). The stakeholder panel reviewed and voted to accept the revisions for both SMPRs® as presented. The next steps would be a Call for Methods for both.

V. NEW WORKING GROUP LAUNCH

2- and 3-MCPD and Glycidyl Esters (GE)

Kate Mastovska (Covance) on behalf of Jan Kuhlmann (SGS Germany GmbH) provided a launch presentation to the stakeholders including technical information, regulatory requirements, and a proposed fitness for purpose for 2 and 3-monochloro-1,2-propanediol (2- and 3-MCPD) and glycidyl esters (GE) in infant formula. The following fitness-for-purpose was reviewed, voted and adopted by the stakeholder panel.

The method should be applicable to the quantitative determination of free 2- and 3-MCPD, 2- and 3-MCPD esters (expressed as 2- and 3-MCPD, respectively) and glycidyl esters (expressed as glycidol) in infant formula, follow-on formula, and – if applicable – also adult nutritionals.

Motion: Brendon Gill moved and Bill Mindak second to adopt the fitness-for-purpose statement. **Motion passed.**

VI. UPDATE ON EXPERT REVIEW PANEL (ERP) STATUS

Darryl Sullivan (Covance) provided the stakeholders a status update on the Expert Review Panel (ERP) activities to take place during the 2017 AOAC Mid-Year Meeting.

VII. TIMELINES/DEADLINES/WRAP-UP

Robert Rankin (INCA) updated the stakeholder community on the future activities for AOAC SPIFAN which included progress to date. SMPRs® for all priority nutrients/groups of nutrients have been developed. There are twenty-two (22) First Action *Official Methods*SM nutrients/groups of nutrients, with Amino Acids, GOS and Vitamin B₃ still awaiting first action methods. There are twelve (12) AOAC Final Action *Official Methods*SM along with the possibility of four (4) additional after the ERP meeting scheduled for March 16, 2017 (Biotin, Chloride, MTE, Vitamin D). Four (4) AOAC SPIFAN methods have been adopted by CODEX as Type II (Vitamin A, Pantothenic Acid, Nucleotides, and Iodine) with four to six (4-6) up for review (Vitamin B₁₂, Fatty Acids, Vitamin E, Myo-inositol, Cr/Mo/Se and Vitamin C).

The proposed action plan includes the AOAC SPIFAN III contract to complete the original AOAC SPIFAN goals (First Action Methods, Final Action Methods, ISO/IDF Standards, CODEX adoption). Create/develop

a forum to evaluate new methods/technologies/opportunities. Facilitate global awareness, acceptance and support of AOAC SPIFAN process & the use of SPIFAN methods and expand vested stakeholders. Review of AOAC Official Methods of Analysis (OMA) Chapter 50 to reflect the AOAC SPIFAN progress.

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