



STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

DRAFT PROCEEDINGS

Meeting at the Sheraton Centre Hotel

123 Queen Street W
Toronto, ON M5H2M9, Canada

Saturday, August 25, 2018

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STAKEHOLDER PANEL MEETING PROCEEDINGS

SPIFAN CHAIR

Darryl Sullivan, Eurofins Food Integrity & Innovation

Stakeholder Attendees:

Claude Aebischerr, <i>DSM</i>	Celine Lesueur, <i>Danone</i>
Jacob Babu, <i>MilkTest NZ</i>	David Levin, <i>Eurofins Food Integrity & Innovation</i>
Lei Bao, <i>Nestlé</i>	Chang Liu, <i>Mead Johnson</i>
Sneh Bhandari, <i>Mérieux NutriSciences</i>	Kai Liu, <i>Eurofins</i>
Keren Breiterman, <i>Eurofins</i>	Chen Liwen, <i>USP</i>
Mark Carkhuff, <i>MilliporeSigma</i>	Rodney Major, <i>Maxxam Analytics</i>
Joana Cavalheiro, <i>Danone Nutricia Research</i>	Elaine Marley, <i>R-Biopharm Rhone Ltd</i>
France Cho, <i>Maxxam Analytics</i>	Sean McClure, <i>Abbott Nutrition</i>
Steven Choquette, <i>NIST</i>	Naren Meruva, <i>Waters</i>
Scott Christiansen, <i>Perrigo</i>	Josh Messerly, <i>Eurofins</i>
Hans Cruijisen, <i>FrieslandCampina</i>	Bill Mindak, <i>Mindak Professional Services, LLC</i>
David Dain, <i>DSM Nutritional Products</i>	Deepali Mohindra, <i>Thermo</i>
Marcel de Vreez, <i>ISO - NEN</i>	Peggy Monson, <i>Abbott Nutrition</i>
Jonathan Draher, <i>Abbott Nutrition</i>	Maria Ofitserova, <i>Pickering Laboratories</i>
Aurelie Dubois, <i>International Dairy Federation</i>	Eystein Oveland, <i>Institute of Marine Research</i>
Ping Feng, <i>Wyeth Nutrition</i>	Shay Phillips, <i>RB MJN</i>
Tetsu Goto, <i>CAC, JP</i>	Melissa Phillips, <i>NIST</i>
Philip Haselberger, <i>Abbott Nutrition</i>	Robert Rankin, <i>INCA</i>
Dirk Hoegaerts, <i>Agilent Technologies Inc.</i>	RJ Raterink, <i>Triskelion B.V.</i>
Steev Holroyd, <i>Fonterra</i>	Alan Roberts, <i>Eurofins Food Integrity & Innovation</i>
Greg Jaudzems, <i>Nestle</i>	Joe Romano, <i>Waters Corporation</i>
Ron Johnson, <i>BioMérieux</i>	Tom Seipelt, <i>Abbott Nutrition</i>
George Joseph, <i>AsureQuality</i>	Yong Shenq Jang, <i>ALL EIGHTS (M) SDN BHD</i>
Estela Kneeteman, <i>INTI</i>	Sean Singh, <i>Synlait Milk Limited</i>
Erik Konings, <i>Nestle Research</i>	Kathryn Stanley, <i>ADM</i>
Joe Konschnik, <i>RESTEK</i>	Yijin Tang, <i>Applied Food Science</i>
Mary K Krogull, <i>Eurofins Scientific Inc.</i>	Joseph Thompson, <i>Abbott Nutrition</i>
Sookwang Lee, <i>FDA</i>	Anders Thomsen, <i>Eurofins</i>
John Lee, <i>Agilent</i>	Marina Torres, <i>LATU</i>

Jeroen van Soest, *Eurofins CCC*
Yannis Vrasidas, *Eurofins*
Wayne Wargo, *Abbott Nutrition*
Kelsey West, *Abbott Nutrition*
Steve Wise, *NIH*

David Woollard, *Hill Laboratories*
Sudhakar Yadlapalli, *First source laboratory solutions*
LLP

AOAC Staff in Attendance

David Schmidt (*Executive Director*)
Delia Boyd
Sharon Brunelle (*AOAC Consultant*)
Scott Coates
Jennifer Diatz
Arlene Fox

Jonathan Goodwin (*Deputy Executive Director*)
Nora Marshall
Deborah McKenzie
Alicia Meiklejohn
La’Kia Phillips
Bob Rathbone

I. WELCOME/INTRODUCTIONS

Darryl Sullivan (Eurofins) chair of the AOAC SPIFAN stakeholder panel welcomed participants to the eighteenth 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 INTERNATIONAL ACTIVITIES

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

Robert Rankin (INCA), Melissa Phillips (NIST) and Darryl Sullivan (Eurofins) provided a joint 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.

There are currently thirteen (13) 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
- **Biotin**
- **Vitamin D**
- **Chloride**

In November 2018, CCNFSDU to introduce AOAC/ISO/IDF methods for Minerals & Trace Elements (2), Folate, Vitamin K, and possibly B Vitamins and Tryptophan and refer to CCMAS.

The next meeting of CCNFSDU40 is November 26-30, 2018 (Berlin), CCMAS40 from May 27-31, 2019 (Budapest), and CAC42 in July 2019 (Rome).

Melissa Phillips provided an update on the Codex STAN 234-1999 with a chart on the distribution of methods and background of the project. AOAC OMB Working Group was formed in June 2017 and developed a rubric for evaluating the existing AOAC methods in STAN 234-1999. Preliminary subject matter experts (SME) conducted reviews of select dairy methods using the rubric. AOAC provided a report to CCMAS on the progress of the dairy methods reviewed along with ISO/IDF in May 2018. With reviews by the SMEs, AOAC revised the rubric which was subsequently approved by OMB for use and distribution to other SDOs in August 2018. Once reviews are completed, recommendations will be prepared and reported to CCMAS40.

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

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

The ISO/TC 34/WG 14 update included publication of the Vitamin C method (ISO 20635:2018) and Vitamin D (ISO 20636:2018) methods as of July 2018; Biotin (ISO/NP 23305) will be reviewed April 2019. The 2018/2019 ISO/IDF meeting is not currently scheduled, SC 5: ISO/IDF June 2019 in Prague and SC HMM and SC AMAC October 2018, WDS, Korea.

The following methods submitted to Codex will be available as IDF/ISO with the next submission to CCNFSDU:

- Vitamin K1
- Minerals & Trace elements by ICP-AES
- Minerals & Trace elements by ICP-MS

c. AOAC INDIA SECTION ACTIVITIES – USE OF AOAC SPIFAN METHODS

Kaushik Banerjee (Past President, AOAC India Section) discussed the Single Lab Validation (SLV) for AOAC Official Method 2011.10 for Vitamin B₁₂, in ‘Indian’ Infant and Pediatric Formulas and Adult Nutritionals, which falls under the mandatory product certification of Bureau of Indian Standards (BIS). The BIS analytical method for B₁₂ (**IS 7529: 1975 RA 2005**), the method for estimation of vitamin B₁₂ in food stuff is based on microbiological method. The principle and challenges of the method was also discussed along with examples of AOAC methods currently used in India. The need for SLV matrices was also discussed and to verify whether it is fit for purpose. Further studies included the SLV protocol, the acceptance criterion as per the SMPR® AOAC 2011.005. The study began in late 2016 after the approval of the protocol; the original method could be extended to child formula, adult nutritional, adult diabetic, and Infant cereal-based products. For malt and malt-based products, there were challenges.

d. UPDATE ON CHINA GUOBIAO (GB) REVISION PROJECT

Cheng-Zhu Liang (Qingdao Customs) provided an update on the GB evaluation program currently under CSIQ. There are over 254 GB analytical methods consisting of chemical and microbiological. CSIQ collect opinions/feedback from authorities and industry and has ten (10) Working Groups with outcomes reported with suggestions for future GB method formulation and revision. Workflows are submitted with Report/Feedback to NHC/CFSA who revise & formulate new GB based on CSIQ’s report. Additional information on the working groups, published evaluated standards, and methods were presented. The presentation also included further discussion in conjunction with the AOAC China Section meeting held during the annual meeting.

III. UPDATE ON MULTI-LABORATORY TESTING (MLT)

Robert Rankin (INCA) provided the stakeholders with a status update on the multi-laboratory testing (MLT). Recently completed MLT studies include Choline, B Vitamins (B₁, B₂, B₃, B₆), and Tryptophan with FOS and Carotenoids (Beta carotene, Lutein, Lycopene) ongoing. These methods are expected to be reviewed by the ERP in March 2019.

IV. 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 final action submissions.

V. NUTRIENT WORKING GROUP UPDATES

Amino Acids

Ping Feng (Wyeth/Nestlé)/Philip Haselberger (Abbott) presented the proposed revisions to Standard Method Performance Requirements (SMPR®) for Determination of Selected Amino Acids in Infant and Adult/Pediatric Nutritional Formula (AOAC SMPR 2014.013). The stakeholder panel requested to remove the footnotes and proposed to split up the groups of amino acids.

Motion: to adopt the modified values of the SMPR® with the removal of the footnotes

Erik Konings moved and Mary Krogull second

Vote: Yes-24/No-1/Abstain-1

VI. UPDATE ON THE NIST STANDARD REFERENCE MATERIALS (SRM)

Melissa Phillips (NIST) updated the stakeholder panel on the current status of the NIST SRM 1869; it is intended to complement the 1849a SRM, not a replacement. It contains all the nutrients from SRM 1849a, and more. The data was combined from NIST methods, manufacturer qualification, two (2) interlaboratory comparisons, LACOMET, and AOAC MLT (vitamin D) with comparison of formula SRMs. The sample was released for sale August 2, 2018 including fluoride, β-carotene, lutein, lycopene, and FOS.

VII. UPDATE ON THE MCPD PROJECT

Katerina Mastovska (Eurofins) provided an update on the AOAC SPIFAN MCPD project including the working group that was launched in March 2017 (WG chair: Jan Kuhlmann, SGS, Germany). The SMPR® AOAC 2017.017 was approved by AOAC SPIFAN in September 2017. A Call for Methods was issued resulting in two (2) methods submitted. The initial Expert Review Panel (ERP) meeting took place in March 2018 with recommendations for both methods. A virtual ERP was held in July 2018 where the methods were adopted AOAC First Action *Official Method*SM status.

VIII. UPDATE ON PROFICIENCY TESTING

Arlene Fox (AOAC) supplied information on the objective of Proficiency Testing to improve analytical performance by providing an independent measure of the quality of the data. Samples were distributed in March 2018 with fourteen (14) laboratories participating; 50% of the laboratories were outside the US and Canada. The next Shipment will be sent September 2018. For future studies, AOAC would like to increase participation, obtain supply of homogeneous stable samples, and ensure that nutrients meet laboratories' needs. As a tool for the future, proficiency testing will evaluate method performance, meet the requirements for accreditation, and support method validation.

IX. STRATEGIC PLANNING UPDATE

David Schmidt (AOAC) discussed the AOAC strategic plan including the mission, vision and goals along with 2018-19 business plan.

X. TIMELINES/DEADLINES/WRAP-UP

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