



STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

DRAFT PROCEEDINGS

Meeting held at:

Atlanta Marriott Marquis
265 Peachtree Center Avenue NW
Atlanta, GA, USA

Saturday, September 23, 2017

AOAC INTERNATIONAL
2275 Research Blvd., Suite 300
Rockville, MD, 20850
UNITED STATES
dboyd@aoac.org
301.924.7077 x126



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SPIFAN CHAIR

Darryl Sullivan, Covance Laboratories

Stakeholder Attendees:

John Austad, <i>Covance</i>	George Joseph, <i>AsureQuality New Zealand</i>
Lei Bao, <i>Nestlé</i>	Estela Kneeteman, <i>INTI</i>
Sneh Bhandari, <i>Mérieux NutriSciences</i>	Erik Konings, <i>Nestlé</i>
Michelle Bugayong, <i>Abbott Nutrition</i>	Mary K. Krogull, <i>Eurofins Scientific, Inc.</i>
Dominik Burger, <i>DSM Nutritional Products</i>	Jan Kuhlmann, <i>SGS, Germany</i>
Anita Burgher, <i>AMB Consulting</i>	Hao Le, <i>National Institute for Food Control</i>
Esther Campos Gimenez, <i>Nestlé</i>	Sookwang Lee, <i>US FDA</i>
Allan Chanady, <i>SCIEX</i>	John Lee, <i>Agilent Technologies</i>
Liwen Chen, <i>USP</i>	Lifu Ma, <i>Certified labs</i>
Chung Cho, <i>US FDA</i>	Elaine Marley, <i>R-Biopharm Rhone Ltd</i>
Robert Clifford, <i>Shimadzu</i>	Katerina Mastovska, <i>Covance</i>
Jo Marie Cook, <i>Florida Dept. of Agriculture</i>	Mary McBride, <i>Agilent</i>
Hans Crujisen, <i>FrieslandCampina</i>	Sean McClure, <i>Abbott Nutrition</i>
Marcel de Vreeze, <i>NEN ISO</i>	Josh Messerly, <i>Eurofins</i>
Jean-Luc Deborde, <i>SCL</i>	Deepali Mohindra, <i>Thermo Fisher Scientific</i>
Jon Draher, <i>Abbott Nutrition</i>	Mardi Mountford, <i>INCA</i>
Aurélie Dubois, <i>International Dairy Federation</i>	Brian Musselman, <i>lonsense</i>
Ping Feng, <i>Wyeth Nutrition</i>	Maria, Ofitserova, <i>Pickering Laboratories</i>
Brendon Gill, <i>Fonterra</i>	Lawrence Pacquette, <i>Abbott nutrition</i>
Mei Gong, <i>METTLER TOLEDO</i>	Arun Paga, <i>Eurofins Central Analytical lab</i>
Eric Gordon, <i>Covance Laboratories</i>	Melissa Phillips, <i>US NIST</i>
Tetsu Goto, <i>CSC</i>	Guenther Raffler, <i>Eurofins</i>
Philip Haselberger, <i>Abbott Nutrition</i>	Robert Rankin, <i>INCA</i>
Steve Holroyd, <i>Fonterra</i>	Klaus Reif, <i>PhytoLab GmbH & Co. KG</i>
Greg Hostetler, <i>Perrigo Nutritionals</i>	Rick Reba, <i>Nestlé</i>
Harvey Indyk, <i>Fonterra</i>	Lars Reimann, <i>Eurofins</i>
Greg Jaudzems, <i>Nestlé</i>	John Reuther, <i>Eurofins</i>
Elaine Jobgen, <i>Eurofins</i>	Joe Romano, <i>Waters Corporation</i>
Ron Johnson, <i>bioMérieux, Inc.</i>	Andre Santos, <i>Agilent Technologies, Inc.</i>

Tom Seipelt, *Abbott Nutrition*
Neil Shepherd, *NATA*
Jeff Shippar, *Covance Labs*
Sean Singh, *Synlait Milk Limited*
Aniko Solyom, *GAAS Analytical*
Karla Steele, *Mead Johnson*
Joan Stevens, *Agilent Technologies*
John Szpylka, *Mérieux NutriSciences*
Jing Tan, *Abbott Nutrition R&D*
Joe Thompson, *Abbott Nutrition*
Marina Torres, *LATU*
Son Tran, *National Institute for Food Control*
Harrie van den Bijgaart, *Qlip BV*
Jeroen van Soest, *Eurofins Food Testing NL*
Martijn Vermeulen, *Ausnutria*
Ioannis Vrasidas, *Eurofins Food Testing Netherlands*
Wayne Wargo, *Abbott Nutrition*

AOAC Staff in Attendance

Delia Boyd
Scott Coates (*CSO*)
Nora Marshall
Deborah McKenzie

Paul Winkler, *SCIEX*
Laura Wood, *US NIST*
Kenny Xie, *US Pharmacopeia*
Sudhakar Yadlapalli, *First Source Laboratory Solutions*
Dorothy Yang, *Agilent Technologies, Inc.*
Jinchuan Yang, *Waters*
Zhenfeng Yue, *Shenzhen CIQ*
Zhiming Zhang, *Agilent*
Lei Zhang, *Alta Scientific*
Jie Zhang, *Mead Johnson Nutrition*
Yi Zhang, *Shenzhen*
Linda Zhao, *Abbott Nutrition*
Hui Zhao, *Covance*
Wei Zhu, *Danone*
Jerry Zweigenbaum, *Agilent Technologies*

Alicia Meiklejohn
Tien Milor
La’Kia Phillips
Bob Rathbone

I. WELCOME/INTRODUCTIONS

Darryl Sullivan (Covance) chair of AOAC SPIFAN stakeholder panel and Ron Johnson (bioMérieux, Inc.), welcomed participants to the sixteenth 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. AOAC SPIFAN OVERVIEW

Darryl Sullivan (Covance) updated the stakeholders with an overview of the accomplishments and provided background information on the AOAC SPIFAN project. Information included engagement of the infant formula industry and current voluntary consensus standards development along with development of the Standard Method Performance Requirement (SMPR®). Activities included the outcomes of the March 2017 AOAC Mid-Year meeting and proposed activities to be held during the 131st AOAC Annual Meeting.

III. AOAC SPIFAN III

Robert Rankin (INCA) provided the stakeholders with the details of the AOAC SPIFAN III contract goals with a forum to accomplish the evaluation of new methods, technologies, and opportunities; the formation of the 2- and 3-MCPD and GE working group was also discussed. The contract also consists of the facilitation of global awareness, acceptance and support of the AOAC SPIFAN process and the use of AOAC SPIFAN methods by ISO/IDF, Codex, and key regions. In addition, the *Official Methods of Analysis*SM (OMA) Chapter 50 will be updated to reflect the AOAC SPIFAN progress.

IV. UPDATE ON INTERNATIONAL ACTIVITIES

a. CODEX REVIEW AND ADOPTION OF AOAC SPIFAN METHODS

Robert Rankin (INCA) continued with background information on the Codex process to date, 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. Proposed methods for other Codex standards will include Infant Formula Section B (FSMP), follow-up formula, and Codex Standard 234-1999.

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 is a total of ten (10) AOAC SPIFAN methods currently in the Codex process as Type II dispute resolution methods:

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

Other methods to be introduced at CCNFSDU in December 2017 includes the AOAC/ISO methods for Vitamin D, Biotin, Chloride, and Minerals & Trace Elements.

b. AOAC/ISO/IDF COOPERATIVE UPDATE

The cooperative update was presented by Marcel de Vreeze (NEN & ISO) with collaboration from Erik Konings (Nestlé) and Harrie van den Bijgaart (Qlip Laboratories). The agreement is to collaborate with AOAC on standard development for harmonization.

The update included new work items for ISO TC 34/WG14 to include Biotin, Folates, Carotenoids. Methods available as ISO/DIS with next submission to CCNFSDU are Vitamin D, Minerals & Trace elements by ICP-AES, Minerals & Trace elements by ICP-MS, and Chloride.

The proposed dates for the next ISO meetings are March 2018 in Gaithersburg, MD (ISO/TC 34/WG 14) and April 23-27, 2018 in Dublin, Ireland (ISO/TC 34/SC5/IDF).

c. AOAC AND CHINA OUTREACH

Linda Zhou (Abbott) on behalf of Dan Schmitz briefed the stakeholders on the current outreach with the Chinese food industry and collaboration with the Chinese Institute of Food Science and Technology (CIFST). CIFST is the largest national food scientific and technical community and a national member of the International Union of Food Science and Technology (IUFoST) since 1984. The organization is comprised of individuals and organizations represented by sub-committees, provincial chapters, and specialized sub-committees covering relevant aspects of food science, technology and industrial sectors. The Chinese Food Industry Overview and CIFST provided focused discussion on the Whey Protein: Casein Ratio analysis method and the Chinese national standards (GB) including definitions and background information on regulations for products and how methods enter the process.

d. NATIONAL INSTITUTE FOR FOOD CONTROL (NIFC)/VIETNAM

Tran Cao Son provided a presentation on NIFC which is Vietnam's national reference food safety laboratory. NIFC activities includes control of food quality and safety, development of new national technical standards for food, and inspection of imported food. NIFC also provides training for the Food Safety Laboratories System along with participation in laboratory assessment, research and other service activities related to food safety.

The Institute uses a wide variety of equipment from mass spectrometry to ELISA based technology and quality management systems (accredited for production along with other QMS systems). Fields of testing encompasses heavy metals, chemical residues, contaminants, GMO, and testing for infant formula, milk and dairy products.

Development of Vietnam's national standards follow international standards such as ISO, EN, AOAC and upgrade from in-housed methods; some AOAC methods are applied in NIFC labs. NIFC also participates in global proficiency testing programs.

NIFC participates in network, international training and workshops with 10-15 courses per year along with the Codex Alimentarius Commission and workshop on harmonization of method performance requirements for food safety testing among APEC economies. In addition, NIFC participates as Codex and AOAC experts, as leading scientists from the food testing laboratories of the APEC economies, policy makers; governmental officials, organizations, universities and research institutes.

V. WORKING GROUP DISCUSSION & CHAIR PRESENTATION AND VOTE ON FINAL SMPR®

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

The 2- and 3-MCPD esters & Glycidyl esters (GE) Standard Method Performance Requirement (SMPR®) was developed by the working group under the AOAC Working Group Initiative based on the needs of the community. The SMPR® was presented, reviewed and subsequently approved by the stakeholder panel. A call for methods based on the pre-approved SMPR® was originally sent to the community, but yielded no methods. Based on discussions, a new call for methods will be sent with the removal of milk powder from the applicability which should also include both free/bound and direct/indirect methods.

Motion: Jan Kuhlmann moved and John Austad second to approve the SMPR® as modified.

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

Working Group Updates

Darryl Sullivan (Covance) and Deborah McKenzie (AOAC) provided an update on the remainder of the nutrients that have not received AOAC First Action *Official Method*SM status to date.

AOAC contacted the working group chairs to discuss revision of their respective Standard Method Performance Requirements (SMPRs®). The SMPRs® for the following nutrients are scheduled to be reviewed by working groups:

- **Amino Acids** (not including Tryptophan) – The Nutrients ERP met in March 2017 to review the amino acids SMPR® and determined that it should be revisited. Unfortunately, the stakeholder panel which is the governing body to review the SMPRs® met prior to the ERP meeting. At this meeting, the stakeholder panel reviewed and resolved that the working group should be convened to revise the SMPR®.

- **Fluoride** – the LOQ is at a very low limit (20mg/100g)

Motion: Jerry Zweigenbaum moved and Erik Konings second to modify the SMPR®.

Yes-17/No-0/Abstain 2 - Motion passed.

- **GOS** – the range of 90-100% is too strict; change to 85% based on recommendation from the working group chair. The working group should re-evaluate the SMPR® based on different products.

Amended Motion: Steve Holroyd moved and John Austad second for the working group to revisit the SMPR®.

Yes-18/No-0/Abstain 2 - Motion passed.

- **Vitamin B₃** – the SMPR® for Vitamin B₃ will not be updated, but the ERP will review methods previously submitted. The working group chair will be consulted.

VI. UPDATE ON INFANT FORMULA PROFICIENCY TESTING (PT) PROGRAM

Darryl Sullivan (Covance) provided the stakeholders a status update on the AOAC Proficiency Testing program. A flyer has been created to provide additional information on the program. A correction was made on the flyer changing vitamin B₃ to vitamin B₆.

VII. UPDATE ON EXPERT REVIEW PANEL (ERP) STATUS

Darryl Sullivan (Covance) provided an update to the stakeholder community on the ERP activities to date and information on methods to be reviewed during the meeting.

VIII. 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/comments.