



STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

DRAFT PROCEEDINGS

Meeting held at:

**Westin Bonaventure Hotel
404 South Figueroa Street
Los Angeles, California 90071**

Saturday, September 26, 2015

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STAKEHOLDER PANEL MEETING PROCEEDINGS

Stakeholder Attendees:

John Austad, *Covance Labs*
Sean Austin, *Nestlé*
Brad Barrett, *Gerstal*
Sneh Bhandari, *Mérieux NutriSciences*
Chris Blake, *Nestlé Research Center*
David Boaz, *Caravan Ingredients*
Francois Bourdichon, *Danone*
Mitch Bowling, *US DEC*
Keren Breiteman, *Eurofins*
Jim Brown, *Sigma-Aldrich*
Kommer Brunt, *Rotating Disc*
Esther Campos-Gimenez, *Nestlé*
France Cho, *Maxxim*
Scott Christiansen, *Perrigo Nutritionals*
Robert Clifford, *Shimadzu*
Hans Cruijssen, *FrieslandCampina*
Raquel de Guzman, *Mead Johnson*
Marieke de Laat, *Mead Johnson*
Marcel de Vreeze, *NEN/ISO*
Jean-Luc deBorde, *SCL*
Xiaojun Deng, *CIQ-Shanghai*
Clay Detlefsen, *National Milk Producers Federation*
Jon DeVries, *Consultant*
Khalil Divan, *Thermo Fisher Scientific*
Wayne Ellefson, *Covance Labs*
Jaap Evers, *Fonterra Cooperative/IDF*
Ping Feng, *Wyeth Nutrition*
Sarwar Gilani, *Consultant*
Brendon Gill, *Fonterra Cooperative*
Don Gilliland, *Abbott Nutrition*
Bill Hammonds, *Mead Johnson*
Steve Holroyd, *Fonterra Cooperative/IDF*
Greg Hostetler, *Perrigo Nutritionals*
Min Huang, *Frontage Labs*
Wes Jacobs, *Abbott Nutrition*
Greg Jaudzems, *Nestlé USA, Inc.*
Elaine Jobgen, *Eurofins*
George Joseph, *AsureQuality*
Estela Kneeteman, *INTI*
Erik Konings, *Nestlé/ISO*
John Lee, *Agilent*
Qi Lin, *Abbott Nutrition*
Adrienne McMahon, *Nestlé/Wyeth Nutrition*
Josh Messerly, *Eurofins*
Dan Meyer, *ADPI*
Bill Mindak, *FDA-CFSAN*
Deepali Mohindra, *Thermo Fisher Scientific*
Mardi Mountford, *INCA*
Brian Musselman, *IonSense*
Norriell Nipales, *Mead Johnson*
Maria Ofitserova, *Pickering Labs*
Lawrence Pacquette, *Abbott Nutrition*
Quangson Pham, *Abbott Nutrition*
Melissa Phillips, *NIST*
Shay Phillips, *Mead Johnson*
Curtis Phinney, *Consultant*
Al Pohland, *Consultant*

Eric Poitevin, *Nestlé*
Robert Rankin, *INCA*
Murali Reddy, *Abbott Nutrition*
Lars Reimann, *Eurofins*
Eric Reyes, *Sigma-Aldrich*
Joe Romano, *Waters Corp.*
Karen Schimpf, *Abbott Nutrition*
Dan Schmitz, *Abbott Nutrition*
Maurice Seegers, *Mead Johnson*
Emma Shi, *CIQ-Shanghai*
Olga Shimelis, *SUPELCO/Sigma-Aldrich*
Matt Sliva, *Perrigo Nutritionals*
Angela Song, *Abbott Nutrition*
Saovaras Srichimuttayomphol, *Mead Johnson*
Monique Steegmans, *Tienen Miher/Beneo Orafiti*
Karla Steele, *Mead Johnson*
Kathy Stenerson, *Sigma-Aldrich*
Darryl Sullivan, *Covance*

Joe Thompson, *Abbott Nutrition*
Marina Torres-Rodriguez, *LATU*
Harrie van den Bijgaart, *Qlip/ISO/IDF*
Wil van Loon, *FrieslandCampina*
Jeroen van Soest, *Eurofins*
Martijn Vermeulen, *TNO Triskelion*
Yannis Vrasidas, *Eurofins*
Mark Wade, *Mead Johnson*
Wayne Wargo, *Abbott Nutrition*
Laura Wood, *NIST*
David Woollard, *Hill Labs, Ltd.*
Chao Wu, *Hilmar Ingredients*
Jason Wubben, *Archer Daniels Midland*
Jinchuan Yang, *Waters Corp.*
Chunyan Zhang, *Abbott Nutrition*
Ziting Zhang, *EUCCC*
Linda Zhao, *Abbott Nutrition*
Yang Zhou, *Eurofins*
Jerry Zweigenbaum, *Agilent*

AOAC Staff in Attendance

Saliha Argubie
Delia Boyd
E. James Bradford (Executive Director)
Scott Coates (CSO)
Jennifer Diatz
Arlene Fox

Evelyn Hernandez
May Jones
Deborah McKenzie
Alicia Meiklejohn
Tien Milor
Bob Rathbone

SPIFAN CHAIR

Darryl Sullivan, Covance Laboratories

I. WELCOME/INTRODUCTIONS

Jim Bradford (AOAC)/Darryl Sullivan (Covance), Chair of the Stakeholder Panel on Infant Formula and Adult Nutrition, introduced and welcomed everyone to the Twelfth stakeholder meeting of AOAC SPIFAN. The voting members in attendance were introduced and recorded for the meeting.

II. SPIFAN OVERVIEW

Darryl Sullivan (Covance) provided a historical perspective on infant formula including regulatory challenges, updated stakeholders with an overview of the accomplishments and achievements in SPIFAN II, provided background information on the SPIFAN project, and current SPIFAN activities during the AOAC Annual Meeting & Exposition. The roles and responsibilities for stakeholder panel, working groups and ERPs were also discussed.

III. WHEY PROTEIN: CASEIN RATIO (WPC) UPDATE

Ziting Zhang (European Union Chamber of Commerce in China) introduced the stakeholder panel to the European Chamber and the Paediatric Nutrition Desk. Ms. Zhang provided an update on the whey protein issue in China which included the background on the current GB methods and the standard of testing methods that are mandatory in China. For milk based infant formulas, the content of whey protein should be over or equal to 60%; a requirement only in the China standard. The current testing methods can cause serious impacts. The general issues observed from industry is the incomparability between GB Method I and Method II.

In addition, WPC methods were not fit for purpose due to a lack of raw materials; China only relies on imported or de-mineralized whey as raw material for whey protein in infant formula. The current suppliers only offer protein data instead of whey protein data. To ensure the whey protein level is in compliance, testing the raw material for whey protein level is logical; otherwise, food fraud is possible if there is no testing.

The timeline of the whey protein testing method was also presented and in December 2014, The GB method was approved by the technical review panel of the Standardisation Administration of China; no final review date has been proposed. Next steps in the effort includes the continued cooperation of AOAC SPIFAN, the progress of the AOAC testing method of whey protein, and the validation of GB Method I by AOAC including reference materials. The EUCCC is an industry association focusing on infant formula in China.

IV. UPDATE ON INTERNATIONAL ACTIVITIES

1. UPDATE ON AOAC SPIFAN FINAL ACTION OFFICIAL METHODS OF ANALYSIS

Darryl Sullivan (Covance) provided the goals and objectives of the AOAC SPIFAN Final Action methods. The ultimate goal of industry is to have the AOAC Final Action *Official Methods of AnalysisSM* (OMA) from AOAC SPIFAN adopted by ISO/IDF also become recognized by the Codex Alimentarius as Type II dispute resolution methods and added to the table of methods of analysis and sampling in the Codex standard for infant formula and formulas for special medical purposes intended for infants. The objectives include AOAC standards development, method evaluation, achievement of AOAC Final Action method status, and publication of method manuscripts. AOAC has entered into an agreement with ISO and IDF to participate in each other's work to jointly develop and approve standards.

2. AOAC/ISO/IDF ACTIVITIES

Erik Konings (ISO) in collaboration with Jaap Evers (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). The November 23, 2015 date is the first opportunity to submit AOAC SPIFAN Final Action methods into the Codex system. Advantages of submission as AOAC/ISO/IDF is globally harmonized dispute resolution methods which increases global availability and accessibility.

V. UPDATE FROM PROFICIENCY TESTING (PT) PROGRAM TASKFORCE

Don Gilliland (Abbott), the PT Working Group Chair provided information on the taskforce including the members and objectives. The taskforce proposed to develop a PT program for infant formula and adult nutritional products utilizing AOAC SPIFAN product matrices. The taskforce also identified the program components including the frequency, products type and number. In addition to establishing nutrient reference values and statistics and reproducibility data, the current AOAC PT program will leverage the expertise. Next steps will be comprised of additional testing, nutrient listing of samples and reference values including number of laboratories. The taskforce proposes the use of the current reproducibility data already completed, evaluation of information required, the forms used and data evaluation to accomplish its goals. These tasks are to be completed by end of 2015.

VI. AOAC ACTIVITIES: BUSINESS DEVELOPMENT REPORT

1. STEPS TOWARDS CONTINUED STANDARDS DEVELOPMENT FOR INFANT FORMULA

Jim Bradford (AOAC) gave a brief update on the lessons learned from the AOAC business development team in discussions with contract research organizations and technology providers to ascertain their issues. The discussions yielded results of contaminants in ingredients that goes across infant formula and foods which was identified as glyphosate (residues in milk powder). Next steps will be to initiate "glyphosate" in milk powder during the Stakeholder Panel on Strategic Food Analytical Methods (SPSFAM) meeting.

2. UPDATE ON THE STAKEHOLDER PANEL ON STRATEGIC FOOD ANALYTICAL METHODS (SPSFAM) ACTIVITIES

Erik Konings (Nestlé) provided information on topics to be covered during the SPSFAM meeting and how some agenda items impact both stakeholder panels. AOAC initiated this panel to address issues of Organizational Affiliate (OA) members, specifically the multi-national food and beverage companies. SPSFAM focuses on the OA issues and builds consensus within the community related to food or strategic growth of the food industry.

The Working Group (WG) initiative was also discussed. The initiative was established December 2014 by the AOAC Board of Directors as an a mechanism for AOAC Organizational Affiliate members to initiate relevant standard development projects using existing AOAC stakeholder panels. The WG supported through AOAC Organizational Affiliates funding and formed through AOAC staff, works with OA's to find additional Organizational Affiliates with the same need for scientifically valid fit for purpose methodology. The WG will develop the SMPR to present to an existing stakeholder panels for review.

The new initiative offers companies the opportunities to solve challenges without waiting on priorities of existing stakeholder panels. WG's funded by current OA's and new companies interested in addressing immediate needs for analytical standards/standard method performance requirements and scientifically valid fit for purpose methodology have a mechanism to accomplish common goals. Glyphosate will be discussed during this meeting under this initiative.

VII. PRESENTATION ON CONTAMINANTS IN MILK/MILK POWDER - CHINA PERSPECTIVE

Yiyin Shi (CIQ-Shanghai) presented on China's perspective including the current status of imports, the legal issues (laws and regulations), supervision, standards and monitoring of dairy products in China.

The current issues include contaminants, micro-organisms, over shelf-life, additives and certificate problems topped the major non-compliance reasons with contaminants the top issue.

VIII. PRIORITIZATION OF CONTAMINANTS IN INGREDIENTS

Darryl Sullivan (Covance) led a focused session on development and prioritization of contaminants in ingredients. Below is the outcome of the deliberations:

1. Nutrients in Ingredients
 - a. Macro nutrients
2. Functional ingredients
3. Extending SPIFAN onto follow-on formulas
4. Evergreen Project
 - a. Proficiency testing
 - b. Training
 - c. Method modernization
5. Contaminants
 - a. Global participation in standards development
 - b. Evaluate risk assessments
 - c. Groups of contaminants
 1. Heavy metals
 2. Pesticides
 3. Mycotoxins
 4. Vet drugs
 5. Anions
 6. MCPD Esters
 7. Food Contact Materials
 8. Environmental contaminants
 9. Allergens
 10. Microbiologics
 11. Adulterants
 12. Authenticity
 13. Additives (colors, flavors, etc.)
 14. Radionuclides
 15. Hormones
 16. Disinfectants

IX. 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.