



# **STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)**

## **DRAFT PROCEEDINGS**

### **Meeting held at:**

**Hilton Washington DC North/Gaithersburg**  
624 Perry Parkway  
Gaithersburg, MD 20877

## **Tuesday, March 17, 2015**

AOAC INTERNATIONAL  
2275 Research Blvd., Suite 300  
Rockville, MD, 20850  
UNITED STATES  
[dboyd@aoac.org](mailto:dboyd@aoac.org)  
301.924.7077 x126



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### STAKEHOLDER PANEL/WORKING GROUP MEETING PROCEEDINGS

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#### Stakeholder Attendees:

Martin Alewijn, <i>RIKILT</i>	Alex Krynitsky, <i>FDA-CFSAN</i>
John Austad, <i>Covance Labs</i>	Markus Lipp, <i>USP</i>
Sean Austin, <i>Nestlé</i>	Frederic Martin, <i>Nestlé Research Center</i>
Brad Barrett, <i>Sciex</i>	Adrienne McMahon, <i>Nestlé Research Center</i>
Anne Bienvenue, <i>U.S. Dairy Export Council</i>	Josh Messerly, <i>Eurofins</i>
Chris Blake, <i>Nestlé Research Center</i>	Paul Milne, <i>Keurig Green Mountain Inc.</i>
Joe Boison, <i>CFIA</i>	Bill Mindak, <i>FDA-CFSAN</i>
Esther Campos-Gimenez, <i>Nestlé</i>	Deepali Mohindra, <i>Thermo Fisher Scientific</i>
Scott Christiansen, <i>Perrigo/PBM Nutritionals</i>	Shu Na, <i>Abbott Nutrition</i>
Jo Marie Cook, <i>FL. Dept. of Agriculture</i>	Matt Noesthede, <i>Sciex</i>
Erin Crowley, <i>Q Labs, Inc.</i>	Mike Nygaard, <i>U.S. Dairy Export Council</i>
Hans Cruijssen, <i>FrieslandCampina</i>	Lawrence Pacquette, <i>Abbott Nutrition</i>
Marcel de Vreeze, <i>NEN/ISO</i>	Shay Phillips, <i>Mead Johnson</i>
Clay Detlefsen, <i>National Milk Producers Federation</i>	Bert Popping, <i>Merieux NutriSciences</i>
Jon DeVries, <i>Medallion Labs/General Mills</i>	Günther Raffler, <i>CLF-Eurofins</i>
Jaap Evers, <i>Fonterra Cooperative/IDF</i>	Robert Ragan, <i>Abbott Nutrition</i>
Jennifer Fruth, <i>Mead Johnson Nutrition</i>	Robert Rankin, <i>INCA</i>
Christophe Fuerer, <i>Nestlé Research Center</i>	Rick Reba, <i>Nestlé USA, Inc.</i>
Jim Harnly, <i>USDA</i>	Murali Reddy, <i>Abbott Nutrition</i>
Steve Holroyd, <i>Fonterra Cooperative</i>	Lars Reimann, <i>Eurofins</i>
Greg Hostetler, <i>Perrigo/PBM Nutritionals</i>	Shauna Roman, <i>Reckitt Benckiser (RB)</i>
Harvey Indyk, <i>Fonterra Cooperative</i>	Joe Romano, <i>Waters Corp.</i>
Wes Jacobs, <i>Abbott Nutrition</i>	Steve Royce, <i>Agilent Technologies, Inc.</i>
Greg Jaudzems, <i>Nestlé USA, Inc.</i>	Louis Salvati, <i>Abbott Nutrition</i>
Ron Johnson, <i>Merieux NutriSciences</i>	Dan Schmitz, <i>Abbott Nutrition</i>
George Joseph, <i>AsureQuality</i>	Olga Shimelis, <i>SUPELCO/Sigma-Aldrich</i>
Estela Kneeteman, <i>INTI</i>	Brian Shira, <i>Mead Johnson</i>
Erik Konings, <i>Nestlé/ISO</i>	David Stone, <i>University of Oregon</i>

Darryl Sullivan, *Covance*  
Fabrizis Suarez, *Abbott Nutrition*  
John Szpylka, *Silliker/Merieux NutriSciences*  
Joe Thompson, *Abbott Nutrition*  
Marina Torres-Rodriguez, *LATU*  
Wil Van Loon, *FrieslandCampina*

Wayne Wargo, *Abbott Nutrition*  
Jon Wong, *FDA-CFSAN*  
David Woollard, *Hill Labs, Ltd.*  
Jinchuan Yang, *Waters Corp.*  
Jupiter Yeung, *Nestlé Nutrition*  
Joyce Zhu, *Jamieson Lab*

**AOAC Staff in Attendance**

Delia Boyd  
Jim Bradford  
Scott Coates  
Arlene Fox  
Deborah McKenzie  
Alicia Meiklejohn  
Tien Milor  
Bob Rathbone

**SPIFAN CHAIR**

Darryl Sullivan, *Covance Laboratories*

**SPIFAN II Nutrient Working Group Chairs (6<sup>th</sup> set of nutrients):**

Louis Salvati, *Abbott Nutrition*

Vitamins B<sub>1</sub>, B<sub>2</sub>, B<sub>3</sub> & B<sub>6</sub>

**Working Group Chairs Sodium Fluoroacetate**

Joe Boison, *CFIA*

Compound 1080

## 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 tenth stakeholder meeting of SPIFAN. The voting members in attendance were introduced and recorded for meeting.

## II. SPIFAN OVERVIEW

Darryl Sullivan (Covance) 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.

## III. WHEY PROTEIN: CASEIN RATIO (WPC) UPDATE

Darryl Sullivan (Covance) provided update on the WPC including background information and potential direction and path forward. WPC methods were not fit for purpose due to lack of raw materials. It was proposed that AOAC SPIFAN Expert Review Panel members review the China GB method(s) and provide feedback and specific comments. AOAC SPIFAN Chair (Darryl Sullivan) and AOAC President (Erik Konings) plan to attend the AOAC China Section meeting to be held April 22-24, 2015 in Suzhou China. Key China officials will be in attendance to discuss the GB method. The industry has been invited to improve the standard and align with next steps.

## IV. AOAC STANDARDS DEVELOPMENT PROCESS OVERVIEW

Deborah McKenzie (AOAC) provided the stakeholder panel an update on the AOAC standards development process which included

## V. SPIFAN WORKING GROUP CHAIR PRESENTATIONS AND VOTE ON FINAL SMPR DOCUMENT

The Working Group Chair (Louis Salvati) presented the recommended SMPRs to the Stakeholder Panel for endorsement.

SMPRs can be found at the following location: <http://stakeholder.aoc.org/SPIFAN/smpr.html>.

### 1. B Vitamins

#### Thiamine

- Footnote 1 – move to applicability statement
- LOQ for Codex (50%)

MOTION to approve the B Vitamins SMPRs with the modifications: *Jon DeVries moved and Melissa Phillips/Bill Mindak second*

**Vote:** Yes – 22 / No – 0 / Abstain – 2

## VI. BACKGROUND INFORMATION ON SODIUM FLUOROACETATE (COMPOUND 1080)

Murali Reddy (Abbott Nutrition) provided background information on the emerging threat in the infant formula industry surrounding the low level pesticide residue. The threat included the adulteration of infant formula with Compound 1080; with an immediate need for standards. The presentation included information on direct or derivatization analysis methods and method requirement for product analysis. Methods are intended to be used for surveillance and monitoring of infant formula.

## WORKING GROUP CHAIR PRESENTATION & VOTE ON FINAL SMPR DOCUMENT

Joe Boison (CFIA) presented to the stakeholder panel, the SMPR for the Sodium Fluoroacetate (Compound 1080) to review/reached consensus and endorse.

### 1. Sodium Fluoroacetate

- Define high throughput
- Change accuracy to recovery

AMENDED MOTION to approve the Sodium Fluoroacetate SMPR with the modification (change accuracy to recovery): *Brad Barrett moved and Joe Romano second*

**Vote:** Yes – 21 / No – 1 / Abstain – 2

## VII. INTRODUCTION OF PROPOSED INFANT FORMULA NUTRITIONAL INGREDIENTS PROGRAM

Darryl Sullivan (Covance) introduced the proposed infant formula nutritional ingredients program to the stakeholders.

### ▪ **PROPOSED INFANT FORMULA NUTRITIONAL INGREDIENTS PROGRAM (*Manufacturer's Perspective*)**

Murali Reddy (Abbott Nutrition) provided information on the proposed nutritional ingredients program including the ensuring of safety and quality of ingredients using standardized methods, analytical technologies and instrumentation, ingredient controls and testing strategies.

### ▪ **GLOBAL DAIRY SECTOR (*IDF Perspective*) & (*ISO/CEN Perspective*)**

Jaap Evers (*IDF*) presented on the International Dairy Federation's perspective on global dairy strategy standards. The organization's vision, role and standards were also discussed. The work in IDF is grouped into nine (9) areas. The global dairy platform was formed in 2006 and members include dairy corporations, cooperatives and associations with a mission to align and support the dairy industry to promote sustainable dairy nutrition. Strategic priorities include nutritional security, sustainability and chain integrity. With the standards strategy, IDF aligns efforts to shape future global regulatory framework, leverage resources and provide nutritional security.

Marcel de Vreeze (*ISO/CEN*) provided information on the CEN's (European standardization organization) perspective. The organization is similar in makeup to ISO with working groups and technical committees/sub committees; examples were provided. The CEN also has agreements with IUPAC along with the Vienna agreement with vertical as well as horizontal standards.

### ▪ **CHALLENGES IN COMPOSITIONAL AND CONTAMINANTS TESTING (*Ingredient Companies Perspective*)**

Hans Cruijisen (FrieslandCampina) provided the ingredient companies perspective in collaboration with Fonterra Cooperative on food quality, safety standards and quality management systems for the assurance of high quality products. The program focused on grass to glass, which included farmer shareholder support with access to a range of services. In addition, the testing (internal and external) and monitoring programs were discussed. Industry wide monitoring systems in various countries to set parameters for environmental and compliance was also presented.

▪ **PRIORITY SESSION ON DAIRY INGREDIENTS**

The stakeholder panel engaged in discussion to establish and prioritize dairy ingredients and contaminants. Darryl Sullivan (Covance) led the session and focused on opportunities and concerns for developing an ingredient program.

- Leverage best practices through the International Dairy Federation (IDF) & the International Special Dietary Industries (ISDI); include broad scope gap analysis
- Other non-governmental organizations should be contacted to assist in providing the framework of the program
- Incorporate requirements into the ingredient program as recommended by the Food Safety Modernization Act (FSMA) effective August 2015. New regulations will include:
  - Requirement of hazard analysis on
    - ◇ chemical
    - ◇ Biological
    - ◇ Radiological
  - Food defense for contamination
  - Whey Protein
  - Antibiotic drug residue testing
- Presentation on background & update on FSMA
- Request that the Food and Drug Administration (FDA) provide information on the implications of FSMA on dairy standards (effective August 2015)
- Identify stakeholders prior to the development of ingredients program
  - Development of the objectives and overall program outline
  - Funding & resources
- Background information on infant formula GMPs
- Consensus on critical parameters to measure
  - Standardizing the test methods
  - Certifying the testing
- Proficiency testing
  - Engage labs to become accredited
- Foreign/domestic supplier verification
- Education/training
  - Align with other resources
- Alignment/focus of analytical methods & regulatory requirements

**VIII. UPDATE ON ISO/IDF/AOAC ACTIVITIES**

Erik Konings (Nestlé) provided an update on the AOAC/ISO/IDF collaboration.

The organization plans to submit the AOAC SPIFAN Final Action methods for endorsement by the CODEX Alimentarius on November 1, 2015. The advantages of submitting the Final Action methods as AOAC/ISO/IDF methods to CODEX is that they become recognized globally harmonized dispute resolution methods and increase global accessibility and availability. The committee that will review the standard for infant formula is the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). They are responsible to assign analytical methods to test the requirements in the CODEX standards. Experts in analytical analysis will review under the CODEX Committee on Methods of Analysis

and Sampling (CCMAS). Currently, eight (8) – ten (10) methods will be submitted for review (based on expert review panel recommendations).

**The timeline for submission include the following:**

- November 1, 2015                      Submit Final Action method into CODEX system
- February 2016                         CCFSDU requests CCMAS for endorsement
- July 2016                                Endorsement of CCMAS recommendations by CODEX

The 2015 timeline includes the meetings of the ISO technical committee (TC 34) and working group (WG 14) in May and October respectively.

**Note:** Place requests to the national standardization bodies (ANSI in US) on how to vote on these standards.