



AOAC INTERNATIONAL

Stakeholder Panel for Infant Formula and Adult Nutritionals (SPIFAN)

Meeting at the Atlanta Marriott Marquis

265 Peachtree Center Ave NE, Atlanta, GA 30303, USA

Tuesday, September 26, 2017 - 8:30am (Eastern US)

REPORT OF THE NUTRIENTS EXPERT REVIEW PANEL (ERP) PROCEEDINGS

Expert Review Panel Members (in attendance):

Darryl Sullivan

John Austad
Sneh Bhandari
Esther Campos-Giménez
Hans Cruijisen/Martine van Gool
Jon DeVries
Karen Schimpf
Harvey Indyk
Estela Kneeteman
Maria Ofitserova
Melissa Phillips/Kate Rimmer
Günther Raffler
David Woollard
Jinchuan Yang
Jie Zhang

Covance Labs (Chair)

Covance Labs
Mérieux NutriSciences
Nestlé
FrieslandCampina
DeVries & Associates
Abbott Nutrition
Fonterra Cooperative
INTI
Pickering Labs, Inc.
NIST
Eurofins/CLF
Eurofins (formerly Hill Labs)
Waters Corp.
Mead Johnson Nutrition

Expert Review Panel Members (unable to attend):

Sean Austin
Scott Christiansen
Brendon Gill
Don Gilliland
Adrienne McMahon
Shay Phillips

Nestlé Research Centre
Perrigo Nutritionals
Fonterra Cooperative
Abbott Nutrition
Wyeth
Mead Johnson Nutrition

AOAC Staff Includes:

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

Nora Marshall
Deborah McKenzie
Alicia Meiklejohn
Tien Milor
Bob Rathbone

Observers:

Keren Breiterman, *Eurofins Scientific*
Michelle Bugayong, *Abbott*
Dominik Burger, *DSM Nutritional Products*
Allan Chanady, *Sciex*
Kelsey Chandler, *Covance Laboratories*
Marcel de Vreeze, *NEN - ISO*
Jean-Luc Deborde, *SCL*
Jonathan DeVries, *DeVries & Associates*
Jon Draher, *Abbott Nutrition*
Ping Feng, *Wyeth Nutrition*
Eric Gordon, *Covance Laboratories*
Tetsu Goto, *CSC*
Philip Haselberger, *Abbott Nutrition*
Greg Hostetler, *Perrigo Nutritionals*
Greg Jaudzems, *Nestlé*
Elaine Jobgen, *Eurofins*
George Joseph, *AsureQuality New Zealand*
Sookwang Lee, *FDA*
Kai Liu, *Eurofins*
Sean McClure, *Abbott Nutrition*
Josh Messerly, *Eurofins*
Deepali Mohindra, *Thermo Scientific*
Nina Skall Neilsen, *NMKL/NordValaInternational*

Eystein Oveland, *NIFES*
Robert Rankin, *INCA*
Aubrey Shahriari, *FDA*
Yiyin Shi, *Shanghai CIQ*
Jeff Shippar, *Covance Laboratories*
Sean Singh, *Synlait Milk Limited*
Angela Song, *Abbott Nutrition*
Karla Steele, *Mead Johnson*
Melissa Thompson, *Covance Laboratories*
Marina Torres, *LATU*
Harrie van Bijgaart, *Qlip BV*
Martine vanGool, *Frieslandcampina*
Martijn Vermeulen, *Ausnutria Hyproca*
Mark Wade, *Mead Johnson Nutrition*
Wayne Wargo, *Abbott Nutrition*
Laura Wood, *NIST*
David Woollard, *Eurofins NZ Laboratories*
Kenny Xie, *United States Pharmacopeial Convention*
Jie Zhang, *Mead Johnson Nutrition*
Linda Zhao, *Abbott Nutrition*
Yang Zhou, *Eurofins Scientific Inc.*
Wei Zhu, *Danone*

I. WELCOME AND INTRODUCTIONS

Darryl Sullivan welcomed all participants to the ERP meeting and introduced the ERP members.

II. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR FIRST ACTION *OFFICIAL METHOD*SM STATUS – AOAC SPIFAN II

For each method, the ERP/Working Group Co-Chairs discussed methods submitted. One (1) method was received and reviewed. No First Action *Official Method*SM status was received.

Method	Method Title	Reviewer(s)	Vote	Comments
Amino Acids	<i>Amino-01 - Single Laboratory Validation Report for Total Amino Acids by UHPLC-UV in Infant Formulas and Adult Nutritionals</i>	Maria Ofitserova Estela Kneeteman	David Woollard (moved) Jinchuan Yang (second) Yes-3/ No-6/Abstain-5 Method not recommended for First Action <i>Official Method</i> SM status <hr/> ERP voted to take no action with comments to method submitter	<ul style="list-style-type: none"> ▪ May need to revise SMPR® for reproducibility per stakeholder panel ▪ Investigate optimizing chromatography (peak Recoveries data and intermediate reproducibility data for many amino acids don't meet SMPR ▪ Method is not suitable for analysis if Tryptophan ▪ The method allows the determination of several amino acids in one single analysis. ▪ The method does not require expensive equipment

III. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR FINAL ACTION *OFFICIAL METHOD*SM STATUS

For each method, the ERP/Working Group Chair will discuss additional information submitted. The Expert Review Panel (ERP) reviewed one (1) methods for modification to include lycopene.

Method	Method Title	Reviewer(s)	Vote	Comments
Carotenoids	<i>OMA# 201613 - Lutein, β-Carotene, and Lycopene in Infant Formula and Adult Nutritionals</i>	David Woollard Karen Schimpf John Austad	David Woollard (moved) John Austad (second) Yes-12/ No-0/Abstain-0 <hr/> Method recommended as a modification for lycopene.	

IV. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR FINAL ACTION *OFFICIAL METHOD*SM STATUS

The Expert Review Panel (ERP) reviewed four (4) methods for Final Action *Official Methods*SM status. All four methods were recommended to the Official Methods Board (OMB) for Final Action *Official Method*SM consideration.

Method	Method Title	Reviewer(s)	Vote	Comments
Carnitine/ Choline	OMA# 2015.10 (Carn-07) - <i>Determination of Free and Total Choline and Carnitine in Infant Formula and Adult/Pediatric Nutritionals by Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)</i>	Günther Raffler Sneh Bhandari	<p>▪ First Round Voting: Günther Raffler (moved) Sneh Bhandari (second) Yes-10/ No-2/Abstain-2</p> <hr/> <p>▪ Second Round Voting: Yes-10/ No-2/Abstain-2</p> <p>Method recommended for Final Action <i>Official Method</i>SM status</p>	<ul style="list-style-type: none"> ○ Method for carnitine only not choline ○ No repeatability data
Folate	OMA# 2011.06 (Fol-22) – <i>Total Folates in Infant Formula and Adult Nutritionals by Trienzyme Extraction and UPLC-MS/MS Quantitation</i>	John Austad Scott Christiansen & Adrienne McMahon (via reviewer forms)	<p>John Austad (moved) Jon DeVries (second) Yes-9/ No-0/Abstain-3</p> <hr/> <p>Method recommended for Final Action <i>Official Method</i>SM status</p>	<ul style="list-style-type: none"> ○ Safety section and reference standard correction for purity and water content has been added to the method ○ Method meets SMPR® applicability statement ○ Long incubation times
MTE	OMA# 2011.14 (MTE-01/03) – <i>Infant formula, Adult nutrition Milk and milk products — Determination of calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium and zinc contents - Inductive coupled plasma atomic emission spectrometric method (ICP-AES)</i>	Jinchuan Yang John Austad	<p>Jinchuan Yang (moved) David Woollard (second) Yes-12/ No-0/Abstain-2</p> <hr/> <p>Method recommended for Final Action <i>Official Method</i>SM status</p>	<ul style="list-style-type: none"> ○ Several samples and elements failed to meet the SMPR® requirements ○ Meets SMPR® for Sodium & phosphorus
Vitamin K	OMA# 2015.09 (VitK-02) – <i>Determination of Trans Vitamin K1 in Infant Formula, Pediatric, and Adult Nutritionals by HPLC and Fluorescence Detection</i>	John Austad Brendon Gill	<p>John Austad (Moved) David Woollard (Second) Yes-11/ No-0/Abstain-1</p> <hr/> <p>Method recommended for Final Action <i>Official Method</i>SM status</p>	<ul style="list-style-type: none"> ○ Needs data for cis ○ Provide instructions to users on how to use the data for both cis & trans ○ Safety concerns are clearly spelled out in the method, no major concerns outside of “normal” lab concerns

V. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR REPRODUCIBILITY TESTING

The ERP collectively discussed the methods and select a single method to move forward through the AOAC SPIFAN process for reproducibility testing.

Method Evaluation Forms - Methods processed via the voting/numbering system:

Method	Method Title	Vote
Carotenoids	2016.13 - <i>Determination of Lutein and β-Carotene in Infant Formula and Adult Nutritionals</i>	755
	2017.04 - <i>Determination of beta-Carotene, Lutein and Lycopene in Infant and Adult/Pediatric Nutritional Formula Using High Performance Liquid Chromatography With UV Detection</i>	705

VI. NEXT STEPS/FEEDBACK FROM EXPERT REVIEW PANEL

Darryl Sullivan provided next steps including Call for Methods for both Carotenoids and Folate (Folic Acid) and suggestions from the Expert Review Panel requesting that the SMPR® for Amino Acids be revisited by the working group.