



AOAC INTERNATIONAL

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

Meeting held at
Boca Raton Resort & Club
Tuesday, September 9, 2014 - 8:30am (Eastern US)

REPORT OF THE EXPERT REVIEW PANEL (ERP) PROCEEDINGS

Expert Review Panel Members (in attendance):

Darryl Sullivan

John Austad
Sneh Bhandari
Esther Campos-Gimenez/Adrienne McMahon
Scott Christiansen
Jon DeVries
Brendon Gill/Harvey Indyk
Sarwar Gilani
Min Huang
Estela Kneeteman
Maria Ofitserova
Melissa Phillips/Kate Rimmer
Shay Phillips
Guenther Raffler
Karen Schimpf
Scott Christiansen
Jinchuan Yang

Covance Labs (Chair)

Covance Labs
Mérieux NutriSciences & OMB
Nestlé/Wyeth Nutrition (formerly Pfizer)
Perrigo/PBM Nutritionals
General Mills/Medallion Labs
Fonterra
Consultant
Frontage Labs, Inc.
INTI
Pickering Labs, Inc.
NIST
Mead Johnson Nutrition
CLF-Eurofins
Abbott Nutrition
Perrigo/PBM Nutritionals
Waters Corp.

Expert Review Panel Members (unable to attend):

Don Gilliland
William Mindak
Jeanne Rader

Abbott Nutrition
FDA
FDA (CFSAN) - Retired

AOAC Staff Includes:

Delia Boyd
E. James Bradford
Scott Coates
Deborah McKenzie
Tien Milor
Anita Mishra
Bob Rathbone

Observers:

Martin Alewijn, *RIKILT*
Sean Austin, *Nestlé Research Center*
Brad Barrett, *ABSciex*
Christopher J. Blake, *Nestlé Research Center*
Martin Bucknall, *UNSW*
Marti Cenky, *Abbott Nutrition*
France Cho, *Maxxam Analytics Inc.*
Mark Collison, *Archer Daniels Midland Co.*
Hans Crujisen, *FrieslandCampina Domo*
Brian De Borba, *Thermo Fisher Scientific*
Jean-Luc Deborde, *SCL Laboratoire de Strasburg*
Rachel de Guzman, *Mead Johnson Nutrition*
Marieke de Laat, *Mead Johnson Nutrition*
XiaoJun Deng, *SHCIQ*
Marcel deVreeze, *NEW/ISO*
Aurélie Dubois-Lozier, *IDF*
Wayne C. Ellefson, *Covance Laboratories*
Jaap Evers, *ISO Rep. (Fonterra Co-op.)*
Ping Feng, *Consultant*
Jennifer Fruth, *Mead Johnson Nutrition*
Pierre-Alain Golay, *Nestlé Research Center*
Phillip Haselberger, *Abbott Nutrition*
Melissa Holskey, *Abbott Nutrition*
Steve Holroyd, *IDF Rep. (Fonterra Co-op.)*
Gregory Hostetler, *Perrigo/PBM Nutritionals*
Wesley Jacobs, *Abbott Nutrition*
Greg Jaudzems, *Nestlé*
Elaine Jobgen, *Eurofins*
George Joseph, *AsureQuality*
Bert Klarenbeek, *FrieslandCampina Domo*
Khammawan Kohler, *Covance Laboratories*
Erik J. M. Konings, *Nestlé Research Center*
Li Xian Liang, *China ChongQing CIQ*
Stephen Lock, *ABSciex*
E. Marley, *R-Biopharm Rhome Ltd. Scotland*
Frederic Martin, *Nestlé Research Center*
Josh Messerly, *Eurofins*
Deepali Mohindra, *Thermo Fisher Scientific*
Nancy Montgomery, *Abbott Nutrition*
Mardi Mountford, *IFC*
Norriel Nipales, *Wyeth Nutrition (formerly Pfizer)*
Lawrence Pacquette, *Abbott Nutrition*
Shang-Jing Pan, *Abbott Nutrition*
Eric Poitevin, *Nestlé Research Center*
Al Poland, *AOAC Consultant*
Robert Rankin, *IFC*
Lars Reimann, *Eurofins*
Joe Romano, *Waters Corporation*
Steve Royce, *Agilent Technologies, Inc.*
Louis Salvati, *Abbott Nutrition*
Dan Schmitz, *Abbott Nutrition*
Matthew Sliva, *Perrigo/PBM Nutritionals*
Angela Song, *Abbott Nutrition*
Karla Steele, *Mead Johnson Nutrition*
John Szpylka, *Merieux NutriSciences*
Joseph J. Thompson, *Abbott Nutrition*
Linda Thompson, *Abbott Nutrition*
Melissa Thompson, *Covance Laboratories*
Laszlo Torma, *Pickering Laboratories, Inc.*
Marina Torres Rodriguez, *LATU*
Martijn Vermeulen, *TNO*
Wayne Wargo, *Abbott Nutrition*
Guy Weerasekera, *Mead Johnson Nutrition*
Laura Wood, *NIST*
David Woollard, *Hill Laboratories*
Wayne Wolf, *USDA (Retired)*
Jinchuan Yang, *Waters Corporation*
Linda Zhao, *Abbott Nutrition*
Yang Zhou, *Eurofins*

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 METHODSM STATUS

For each method, the ERP/Working Group Co-Chairs discussed methods submitted.

- **Folate – Chair:** Erik Konings (Nestlé)
Fol-20: Method was withdrawn for additional information

- **Carnitine – Co-Chairs:** John Austad (Covance) & Günther Raffler (CLF-Eurofins)
Choline – Co-Chair: Sneha Bhandari (Silliker) & Nick Cellar (Abbott)

 - Instructions to study directors to collect choline data as well as carnitine

Method	Method Title	Reviewer(s)	N Vote	Comments
Folate	<i>Fol-20 - Analysis of Folic acid and 5-Methyltetrahydrofolate in Infant and Adult Nutritional formula using Ultra-Performance Liquid Chromatography-Tandem Mass Spectrometry</i>	Adrienne McMahon Min Huang	Method withdrawn from consideration	<ul style="list-style-type: none"> ◇ SPIFAN matrices did not produce internal peaks (repeat work) ◇ Concerned with interferences ◇ Confirmation ion is required ◇ Did not meet LOQ
Carnitine	<i>Carn-05 - Single Laboratory Validation of CARN-05: Determination of Free and Total Carnitine and Choline in Infant Formulas and Adult Nutritional Products</i>	John Austad Sneha Bhandari	John Austad moved & Sneha Bhandari second *Motion: move method to First Action Official Method SM status Yes- 14/ No-0 /Abstain-1	<ul style="list-style-type: none"> ◇ Collect choline data as well as carnitine ◇ Will not be considered dispute resolution method for choline ◇ Investigate choline adult powder milk
	<i>Carn-06 - Simultaneous Determination of Carnitine and choline in Infant Formula, Adult/Pediatric Nutritional Formula, food and feed ESI LC-MS/MS</i>	Günther Raffler John Austad	Method not recommended at this time	<ul style="list-style-type: none"> ◇ Collect choline data as well as carnitine ◇ Recoveries needed at different levels ◇ Must use SPIFAN matrices ◇ Need SPIFAN data ◇ Resubmit for March 2015

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

The Expert Review Panel (ERP) reviewed seven (7) methods for Final Action *Official Methods*SM status. Six (6) were recommended for Final Action to the Official Methods Board (OMB).

Method	Method Title	Reviewer(s)	Vote	Comments
<i>Vitamin B₁₂</i>	<i>2011.10 - Vitamin B₁₂: - Determination of Vitamin B12 in Infant Formula and Adult Nutritionals by HPLC</i>	John DeVries Shay Phillips	John DeVries moved & Scott Christiansen second *Motion: move to Final Action Yes- 11/ No-1 /Abstain-3 *Second vote: Yes- 11/ No-1 /Abstain-3	◇ Question about SPE overload – How to qualify ◇ Include safety for cyanide ◇ Chromatography resolution
<i>Vitamin D</i>	<i>2011.11 - Vitamin D - Determination of Vitamin D2 and D3 in Infant and Adult/Pediatric Nutritionals and Utilizing Ultra High Performance Liquid Chromatography/Tandem Mass Spectrometry (UHPLC-MS/MS)</i>	Sneh Bhandari Brendon Gill/ Harvey Indyk	Sneh Bhandari moved & Sarwar Gilani second *Motion: move to Final Action ~Motion: withdrawn	◇ Editorial changes ◇ Method not a significant improvement over existing method(s) ◇ 50% of samples do not apply to SMPR ◇ Qualifier removed ◇ Single platform – Blinded
<i>Inositol</i>	<i>2011.18 - Inositol - Determination of Myo-Inositol (Free and Bound as Phosphatidylinositol) in Infant Formula and Adult Nutritionals by Liquid Chromatography/Pulsed Amperometry with Column Switching</i>	Brendon Gill/ Harvey Indyk	Esther Campos-Gimenez moved & Melissa Phillips second *Motion: move to Final Action Yes- 12/ No-1 /Abstain-2 *Second vote: Yes- 12/ No-1 /Abstain-2	◇ Remove phosphatidylinositol (data does not support) ◇ Method does not match SMPR ◇ Sum of free myo-inositol (change total to free in method) ◇ Remove “phosphorylated forms” from applicability section ◇ Sum and Free and phosphydal Inositol; capture in applicability statement of SMPR.
<i>UTM</i>	<i>2011.19 - Ultra Trace Minerals - Simultaneous Determination of Chromium, Selenium, and Molybdenum in Infant Formula and Adult/Pediatric Nutritional Formula by Inductively Coupled Plasma/Mass Spectrometry</i>	Min Huang Sneh Bhandari	Min Huang moved & Sneh Bhandari second *Motion: move to Final Action Yes- 13/ No-0 /Abstain-1	
<i>Nucleotides</i>	<i>2011.20 - Nucleotides - Nucleotides in Infant Formula by HPLC-UV</i>	Sneh Bhandari Estela Kneeteman	Sneh Bhandari moved & Estela Kneeteman second *Motion: move to Final Action Yes- 13/ No-0 /Abstain-1	

<i>Vitamin A/E</i>	<i>2012.10 - Vitamin A/E - Simultaneous Determination of 13-Cis and all-trans Vitamin A Palmitate (retinyl palmitate), Vitamin A Acetate (retinyl acetate), and Total Vitamin E (α-Tocopherol and DL-α-Tocopherol Acetate) in Infant Formula and Adult Nutritionals by Normal Phase HPLC</i>	Scott Christiansen Jinchuan Yang	Scott Christiansen moved & Brendon Gill second *Motion: move to Final Action Yes- 13/ No-0 /Abstain-1	◇ Require use of primary standards ◇ Simplify calibration curve (all trans)
<i>Fatty Acids</i>	<i>2012.13 - Fatty Acids - Determination of Fatty Acids, including LCPUFAs, in Infant and Adult/Pediatric Nutritional Formula</i>	Jon DeVries Karen Schimpf	Jon DeVries moved & Karen Schimpf second *Motion: move to Final Action Yes- 13/ No-0 /Abstain-1	◇ Reference materials with higher RSD ◇ Double check chromatography for clarity (peaks)

IV. NEXT STEPS/FEEDBACK FROM ERP

Darryl Sullivan provided next steps including deadline dates. The ERP provided feedback on lessons learned from reviews.